

PROCEDURE

Research Management - Biospecimen Ethics and Participant Information and Consent Form

PR2017/115
Version No. 1.0

PURPOSE

This Procedure is intended to outline general principles that can be used in most situations to ensure that the interests of the participant are safeguarded in obtaining voluntary and informed consent from Metro South Health research project participants.

This Procedure applies to major ethical considerations and participant consent issues that arise in the conduct of tissue banking, tumour banking, biobanking and/or collections of biospecimens and/or research. The issues concern Principal Investigator-ship, risk, confidentiality, consent and quality of research. It also outlines best practices for the process of obtaining informed and voluntary consent from the participants, for the acquisition of participant clinical data and biospecimens surplus to clinical requirements, specifically for use in medical research.

It should be noted that the National Statement on Ethical Conduct in Human Research (2007) ("National Statement") (2.2) addresses the issue of informed consent comprehensively. Whilst the Metro South Health Human Research Ethics Committee (HREC) Office/r recommends the use of the National Health and Medical Research Council (NHMRC) endorsed standardised Participant Information and Consent Forms ([PICFs](#)) this Procedure is intended to provide a summary relevant to Metro South Health research projects in the collection of biospecimens but does not supersede in any way the National Statement.

OUTCOME

Adherence to this Procedure will ensure all research conducted within Metro South Health or in collaboration with external entities, is of the highest ethical and scientific standard and is compliant with relevant legislation, standards and guidelines.

This Procedure applies to:

- All Metro South Health employees who conduct human research within or in association with Metro South Health facilities, or through access to Metro South Health participants; and
- All personnel (including researchers, students and visitors) involved in all aspects of human research in or in association with Metro South Health.

Failure to comply with this Procedure may amount to research misconduct on the part of the responsible individual. This Procedure must be read in conjunction with other Metro South Health Research Management Procedures.

KEY PRINCIPLES

The following key principles guide Metro South Health employees in ethical considerations in the collection of biospecimens from Metro South Health participants and in the drafting of PICFs:

- Principal Investigators must ensure prior, free and informed consent is obtained from each participant or where applicable, from an appropriate substitute decision-maker.
- Where stored biospecimens are available for use in research, Metro South Health must have processes in place for ensuring the research has been approved in accordance with the National Statement.
- Participant recruitment must be carried out in a non-coercive and equitable manner whilst being mindful of power relationships. During the recruitment process there are different ways to ensure the research practices are independent of clinical practices (e.g. the person performing the recruitment is independent from the lead investigator). It should always be made clear to potential participants that agreement or refusal to participate will not have any affect on their medical care.
- While the goal of the informed consent process should be to provide as much information as is relevant, the document provided must remain as straight-forward, readable and accessible as possible.
- Participants must be given enough time to make an informed decision and have all questions answered prior to giving consent.
- Participants must not be paid for their participation in a Metro South Health research project however, if approved by an accredited HREC participants may be reimbursed for reasonable costs incurred in their participation in research (e.g. transport, parking), and to be paid for their time, provided that the payment is not disproportionate or an inducement to take risks or participant in the research project.
- Where a potential participant lacks the capacity to consent (e.g. due to age or mental incapacity), a person or appropriate statutory body exercising lawful authority for that individual should be provided with relevant information to decide whether he or she will participate.
- Principal Investigators must ensure clear, detailed, publicly available Standing Operating Procedures (SOPs) are in place regarding recruitment, participation and the process of informed consent.
- Research projects must take reasonable measures to avoid discrimination against or stigmatisation of a person, family or group whether or not they have contributed to the collection.
- Communication strategies must take into consideration the different needs of participants including health literacy.
- For all new Metro South Health research biorepositories, Principal Investigators must seek broad and enduring consent for the storage and future use of biospecimens. If tiered consent has been previously used in exceptional circumstances, robust systems should be in place to manage participants' wishes, please see [Section 2.2 Broad and Enduring Consent](#) for more information. Retrospective re-consent of participants for existing collections is not recommended unless participants are being contacted for other reasons. Changes to the consent process will require ethical review.
- Principal Investigator must have a clearly articulated SOP on whether participants may be re-contacted during the course of the research project's existence, the situations for which re-contact will be permitted, and the conditions that will govern re-contact.

LEGISLATION OR OTHER AUTHORITY

Legislation

- *Defence Trade Controls Act 2012 (Cth)*
- *Gene Technology Act 2000 (Cth)*
- *Gene Technology (Queensland) Act 2016 (Qld)*
- *Hospital and Health Boards Act 2011 (Qld)*
- *Information Privacy Act 2009 (Qld)*
- *Privacy Act 1988 (Cth)*
- *Public Health Act 2005 (Qld)*
- *Therapeutic Goods Act 1989 (Cth)*
- *Transplantation and Anatomy Act 1979 (Qld)*

Regulation

- Gene Technology Regulations 2001 (Cth)
- Information Privacy Regulation 2009 (Qld)
- Therapeutic Good (Medical Devices) Regulations 2002 (Cth)
- Therapeutic Goods Regulations 1990 (Cth)
- Transplantation and Anatomy Regulation 2004 (Qld)

Statements, Papers and Guidelines

- [Canadian Tissue Repository Network Policies and Procedures](#)
- Government of Western Australia: [Guidelines for Human biobanks, genetic research databases and associated data](#)
- International Society for Biological and Environmental Repositories (ISBER): [Best Practices for Repositories 2012: Collection, Storage, Retrieval and Distribution of Biological Materials for Research](#)
- Medical Research Council: Human Tissue and Biological Samples for Use in Research: [Operational and Ethical Guidelines](#)
- National Health and Medical Research Council (NHMRC):
 - [Australian Code for the Responsible Conduct of Research 2007](#)
 - [National Statement on Ethical Conduct in Human Research \(2007\) - Updated May 2015](#)
 - [Research Governance Handbook: Guidance for the national approach to single ethical review 2011](#)
 - [Guidance: Safety monitoring and reporting in clinical trials involving therapeutic goods](#)
 - [Values and Ethics - Guidelines for Ethical Conduct in Aboriginal and Torres Strait Islander Health Research 2003](#)
 - [Biobanks Information Paper 2010](#)
 - [Ethics and the Exchange and Commercialisation of Products Derived from Human Tissue – Background and Issues October 2011](#)
- Organisation for Economic Co-operation and Development (OECD): [Guidelines on Human Biobanks and Genetic Research Databases](#)
- Queensland Biotechnology Code of Ethics: [Update of the Code of Ethical Practice for Biotechnology in Queensland](#)

- Queensland Government: [Queensland Biotechnology Code of Ethics: Update of the Code of Ethical Practice for Biotechnology in Queensland \(2006\)](#)
- Queensland Health: [Health Service Directive: Research Ethics and Governance HSD-035:2016](#)
- The Royal College of Pathologists of Australasia: [Biobanking Guideline 2014](#)
- Therapeutic Goods Administration: [Note for Guidance on Good Clinical Practice \(CPMP/ICH/135/95\) 2000 - Annotated with TGA Comments](#)

Metro South Health Policies, Procedures, Manuals, Frameworks etc.

- [Management of Conflict of Interest - All Staff Procedure \(PR2016-66\)](#)
- [Management of Conflict of Interest Policy \(PL 2014/0038\)](#)
- [Research Biorepositories Policy \(PL2017/53\)](#)
- [Research Biorepositories - Establishment of a Research Biorepository Procedure \(PR2017/100\)](#)
- [Research Biorepositories - Databases, Tracking, Records and Documentation Procedure \(PR2017/109\)](#)
- [Research Biorepositories - Disposal, Lab/Fridge Merge and Closure Procedure \(PR2017/105\)](#)
- [Research Biorepositories - Material Transfer Agreements, Packaging and Shipping Procedure \(PR2017/107\)](#)
- [Research Biorepositories - Operational Arrangements Procedure \(PR2017/101\)](#)

RESPONSIBILITIES

Executive Management Team

Must ensure all research projects established in Metro South Health are consistently operated in accordance with collaborative, harmonised, clear and detailed publicly available Policies, Procedures, Research Protocols and SOPs.

Centres for Health Research

Support Principal Investigators in the ethical arrangements of each research project through the provision of guidance and support when interpreting principles and provisions contained within the Metro South Health Research Management Compliance Framework.

Metro South Health HREC

Ethically review Metro South Health research project Human Research Ethics Applications (HREAs) and associated documents (e.g. Research Protocol, PICF and Curriculum Vitae) when required.

Principal Investigator - Responsible Officer

Ensure that the research project is operated ethically and in accordance with the National Statement.

Research Biorepository Laboratory Manager

Ensure that the research biorepository is operated ethically and in accordance with the National Statement (if applicable).

Laboratory Technician/Technologist Assistant/Clinical Personnel

Ensure that the research biorepository is operated ethically and in accordance with the National Statement (if applicable).

Researchers

Adhere to all relevant Policies, Procedures, Research Protocols and SOPs when undertaking research in Metro South Health.

Personnel Involved in the Ethics and PICF Process

Abide by all principles outlined in the National Statement.

SUPPORTING DOCUMENTS

Attachment 1 - [Application](#)

Attachment 2 - [Metro South Health Participant Information and Consent Form Template](#)

Attachment 3 - [Participant Information and Consent Form Compliance Tool](#)

DEFINITIONS

See the [Metro South Health Research Management Glossary](#)

PROCEDURE - Biospecimen Ethics and Participant Information and Consent Form

STEP 1: Establishment

At the time of establishment, a Metro South Health research project must develop a PICF. The informed consent materials should be written in clear, concise and simple language. The Metro South Health Participant Information and Consent Form Template ([Attachment 2](#)) may be used, or alternatively, a Principal Investigator may develop their own.

If developing a project specific PICF then all principles of the National Statement must be incorporated and provisions outlined in this Procedure may be utilised.

The Participant Information and Consent Form Compliance Tool ([Attachment 3](#)) can be utilised to ensure compliance with the National Statement.

During the consent process participants must be provided with information about (including but not limited to):

- The purpose of the program.
- The type and expected amount of the biospecimen to be taken, if applicable.
- The manner in which the biospecimen will be taken, the safety and invasiveness of acquisition, and the duration and conditions of storage.
- The potential uses for the biospecimen as known (objectives of research).
- The potential users of the research project (academic and commercial users).
- Potential risks and benefits if any to the participant.
- Storage and duration of storage.
- Data to be collected (i.e. health and other records to be accessed) and data anticipated to be derived from the analysis of samples.

- As known, who will access tissue, personal clinical and research information, what information will be obtained and how the participant's privacy and confidentiality will be protected.
- How surplus material will be disposed of should it be no longer needed.

STEP 2: Broad and Enduring Consent

The Principal Investigator must consider obtaining a consent that will permit biospecimens and/or data to be used to address unforeseen research questions. Participants must be fully informed of the breadth of such consent and there must be additional safeguards in place to ensure that participants are protected. The Principal Investigator must also consider ethical considerations specific to participants when developing relevant PICFs.

STEP 3: HREC

Prior to collecting commencing research or samples the written PICF and any other written information to be provided to the participants must have the written approval/favourable opinion of an appropriate HREC. Please see [Ethical and Scientific Review of Human Research Procedure \(PR2017/113\)](#) for more information.

STEP 4: Waiver of Consent

Under certain circumstances, the HREC may provide a waiver of consent. Researchers must contact the Metro South Health HREC Office/r via telephone (07) 3443 8049 or email EthicsResearch.PAH@health.qld.gov.au to discuss the proposed research project and identify whether a waiver of consent is appropriate under relevant circumstances.

STEP 5: Standard Operating Procedures

The Principal Investigator must ensure there are SOPs in place on participation. Research projects involving participants who are minors must have a clearly articulated SOP on whether, when and how the minor's assent will be obtained, in accordance with applicable law and ethical principles. Involving participants who are minors or with impaired decision-making capacity should have a clearly articulated SOP on what steps will be taken, in accordance with applicable law and ethical principles, once such participants become legally competent to consent. Please see [Specific Human and Animal Ethical and Scientific Review Requirements Procedure \(PR2017/114\)](#) for more information.

Additionally the research project must have a clearly articulated SOP on feedback and the nature of the feedback, if any, that will be provided to participants. SOPs must also be in place ensuring that any re-contacting is not unduly burdensome for participants and is carried out by research project representatives or designees trained in dealing with sensitive issues and impartial in regards to the outcome of the research.

STEP 6: Obtaining Consent

The collection and use of human tissue for research must be undertaken with voluntary and informed consent of competent participants (i.e. a person who is the age 18 years and is of sound mind) following the receipt of medical advice provided by a registered health practitioner. Consent must also be obtained to collect or access personal and clinical information from medical records. Consent in the context of long-term collections of biospecimens, such as research biorepositories, is to see it as having two (2) components (using the terminology of the National Statement):

- specific consent to the taking of the biospecimen and related information and for storage; and
- unspecified or broad consent to the use of data for future, as yet undetermined, research.

Please see procedures contained within the Metro South Health Research Biorepository Governance Framework for more information.

Information provided to potential participants needs to be clear, explicit, and concise and in simple language. Consent must be obtained voluntarily, without manipulation, influence or coercion. It must also be made clear that a participant can revoke consent at any time, and that a decision not to participate in the program will in no way compromise the standard of medical care the participant will receive. Prior to requesting signed consent the Principal Investigator must ensure participants are provided with detailed information.

STEP 7: Registered Health Practitioner and/or Appropriately Authorised/Qualified Scientific Employee

When seeking consent, information for participants, legally acceptable representatives, impartial witnesses or an intermediary should be presented in a clear form that can be easily understood. Lack of proficiency in the operating language should not disqualify participants. In this case, an intermediary competent in the language should translate the relevant information and the participant should acknowledge in his or her language an understanding of the research project, the extent of his or her participation, the risks involved and freely give consent.

A registered health practitioner and/or appropriately authorised/qualified scientific employee is not only certifying that the consent was given in their presence but is also stating that they are satisfied that the participant is aged 18 years or older, at that time the person was of sound mind, consent was freely given and that medical advice has been duly furnished to the person. Consent to remove biospecimens from a participant's body must be obtained in writing and signed in the presence of a registered health practitioner and/or appropriately authorised/qualified scientific employee.

STEP 8: Removal of Biospecimens

Only after consent has been received in accordance with the above principles can biospecimens be removed, as specified in the consent, and stored for scientific purposes.

STEP 9: Retention

All biospecimens contained within a Metro South Health research biorepository must have a traceable PICF associated with the participant.

STEP 10: Revision

Any revisions to the informed consent form or the written information must receive the HREC approval/favourable opinion in advance of use. Where subsequent use of biospecimens or data is envisaged that would not be consistent with the original informed consent, a new consent should be obtained from the participant or from the appropriate substitute decision-maker, or a waiver of consent should be obtained from a HREC or an appropriate authority, in accordance with applicable law and ethical principles pertaining to the protection of human subjects.

PROCEDURE DETAILS

Procedure Number

PR2017/115

Procedure Name

Metro South Health Research Management -
Biospecimen Ethics and Participant Information
and Consent Form Procedure

Policy Reference

PL2017/55

Metro South Health Research Management
Policy

Supersedes

Nil

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ATTACHMENT 1 - APPLICATION

1.0 Legal and Ethical Issues

Ethics in human subjects' research includes several fundamental key concepts:

- Freely-given informed consent is necessary before research on humans may be conducted.
- Research must be well designed, conducted by persons with appropriate expertise and lead to meaningful conclusions.
- Every effort must be taken to reduce the risks to participants and ensure that the risks do not exceed the benefit of the expected findings.
- Studies in animals must provide reason to believe that the study of humans is needed and is the only way to get the necessary information.

1.1 Collection of Biospecimens

The collection, storage, distribution and use of biospecimens in research raises many legal and ethical issues with research biorepositories often serving as the intermediary between research project participants and the scientific research community.

The collection, storage and use of biospecimens and associated data must be conducted in a way that respects the individual and maintains privacy and confidentiality. In addition, research biorepositories must adhere to and keep up-to-date on relevant national regulations, privacy regulations and other relevant national, state and local laws. Regulations that govern the collection and import and/or export of biospecimens must also be observed. Please see the [Metro South Health Research Biorepositories - Material Transfer Agreements, Packaging and Shipping Procedure \(PR2017/107\)](#) for more information.

1.2 Human Research Ethics Committee (HREC)

The use of biospecimens and accompanying data is critical for medical research. The public and program participants must have confidence that research projects and researchers will use and handle such material according to recognised ethical standards. It is important to ensure that collections of biospecimens are used ethically and optimally for the research to benefit health and knowledge. The interests of the participants should always take precedence over the interests of research, science and society.

A HREC is a group formally designated by an institution to review biomedical research involving humans, to approve the initiation of the research and conduct periodic review of such research. The safety, rights, dignity and well-being of participants and researchers must always be safeguarded. A route to support transparency is to ensure that research involving biospecimen undergoes an independent ethical review. The following principles in areas requiring ethical consideration guide Metro South Health research projects in collecting, maintaining and managing the resource it controls:

- To ensure that the interests of the participant are safeguarded, processes, Research Protocols and relevant SOPs such as consent, collection, storage, distribution and use must be reviewed, evaluated and approved by the Metro South Health HREC and/or by the relevant HREC, of the applicable institution, to ensure that these processes are appropriate to protect human subjects.

- The standard of “minimal risk” must be considered in the review process. The physical risks in donating tissue samples for research may be minimal, but the risk that information from research on the sample and annotated data could harm the privacy and confidentiality of the participant must be considered.
- Biospecimens and annotation data collection must be conducted under HREC approved collection protocols. Typically this will involve obtaining informed consent directly from participants. Participants should be informed and understand what the tissue sample is to be used for. In some circumstances a HREC may provide a “waiver of consent” on behalf of the participants.

There are certain low risk situations where HREC review may not be legally or ethically necessary. For example when samples are being used within the terms of consent and there are underpinning governance structures that ensure this, and the research team are not able to identify participants. All direct approaches to participants and consent procedures should be reviewed by a HREC. Please see [Ethical and Scientific Review of Human Research Procedure \(PR2017/113\)](#) for more information.

1.3 Confidentiality

Personal and medical information and research results relating to the participant and biospecimen must always be treated as confidential. The participant must be made aware of the type of personal and medical information that will be used by researchers, and what safeguards will be in place to protect their confidentiality and anonymity. Researchers must not disclose to any person any information or documents whereby the identity of the participant may become publically known.

The Principal Investigator must disclose to participants, insofar as possible, the exceptional conditions under which researchers may be provided access to biospecimens or data that is not coded or anonymised. Principal Investigators must have in place protocols and processes to protect participants’ personal and medical information, including, but not limited to genetic information. Please see Metro South Health Research Biorepositories - [Databases, Tracking, Records and Documentation Procedure \(PR2017/109\)](#) for more information.

1.4 Protection from Research Risks

Care must be taken to minimise the risks to participants, and ensure that risks do not outweigh the benefits of the expected findings from research projects using the biospecimens. This includes minimising physical risks and psychosocial risks associated with the collection of biospecimens and/or data and ensuring that the collection of biospecimens and data does not affect patient care.

The research project must follow well-documented processes to protect the privacy and confidentiality of the participants from whom the biospecimens and/or data are obtained. Such processes may include:

- completely anonymising biospecimens and data;
- assigning a unique code and/or removing all identifying information from the biospecimens and data;
- storing biospecimens and data securely;
- restricting access to biospecimens and/or data; and
- providing firewalls between the subject identity and the recipient investigator.

Such firewalls prevent inappropriate data from passing in either direction through the firewall (e.g. identifying information to the researcher or specific research results that have not been validated to the participant).

In addition, identifying information must be removed before allowing the recipient investigator to have access to biospecimens and/or data, unless the investigator has HREC approval to have access to this information.

The collection of biospecimens and/or data for research must never adversely affect patient care. Every effort should be made to protect the privacy and confidentiality of data associated with the biospecimens. Please see Metro South Health Research Biorepositories - [Databases, Tracking, Records and Documentation Procedure \(PR2017/109\)](#) for more information.

1.5 Third Party Access

Participants must be informed of whether or not their biospecimens and data, in whole or in part, will be made accessible to third parties, insurance providers or law enforcement agencies for non-research purposes and the conditions under which this may occur. Metro South Health must not disclose personal, identifying data from genetic tests to third parties without consent of the individuals concerned; restrictions on disclosure are necessary to maintain patient confidentiality and ensure that the results of genetic testing are not used to stigmatise individuals or cause discrimination (e.g. with respect to accessing life insurance or employment).

1.6 Economic Factors

Economic factors may provide motivation for participants to provide biospecimens but this could compromise the quality and safety of the collection. Participants must not be offered or receive any financial compensation for participation in the research project. Biospecimens collected from participants should be treated as gifts. While participants should not be paid for their participation, reimbursement of reasonable costs incurred in order to contribute to the research project is acceptable. Such compensation should not be of a magnitude so as to provide inducement to participate.

Biospecimens should not give rise to financial gain. Metro South Health research projects must not sell (for a profit) samples of biospecimens that they have collected. A reasonable payment from users of the Metro South Health research biorepository to recover costs of obtaining, managing, maintaining, processing and handling the collection is however acceptable. Please see Metro South Health Research Biorepositories - [Operational Arrangements Procedure \(PR2017/101\)](#) for more information.

1.7 Commercialisation and Intellectual Property Issues

Participants must be informed in the consent process, that biospecimens or their products may be used by academic researchers as well as researchers in the commercial sector and that they will not be entitled to a share of the profits that may ensue from research. Disclosure that there is the possibility or intent to commercialise research might help alleviate ethical concerns that participants are not aware of intended uses of their tissue.

Participants must also be provided with information about commercial products that may arise from research conducted using its resources, including biospecimens, data derived from the analysis of samples, data or other information provided by or about the participant. Information should also be provided on the benefits, if any, the participant may receive. Please see Metro South Health Research Biorepositories - [Operational Arrangements Procedure \(PR2017/101\)](#) for more information.

1.8 Waiver

Consent must be given by an appropriate person. Usually this would be the participant themselves, or if they are not able to do so the appropriate proxies should be consulted. Metro South Health acknowledges the importance of many existing collections of biospecimens (including pathology archives) in supporting research, even when consent is not in place or is not practicable, desirable or ethical to obtain retrospectively.

There are also times when it is not practicable to obtain consent and it is considered ethical to use samples for research without consent. In this case, research without consent can be undertaken provided the legal requirements are followed, the proposed use of samples (without consent) can be justified and use would be considered ethical and reasonable.

Metro South Health proposes two (2) approaches to 'reasonableness':

- 1) The stronger test - would a reasonable person have refused to allow their samples to be used, if you had asked them?
- 2) Would a reasonable person be distressed if they discovered that their samples had been used without their consent?

Researchers should consider both justification and reasonableness in proposals when intending to use biospecimen without consent, and ensure that the confidentiality of all participants and their associated health and research information is maintained.

A HREC will decide whether research use without consent is appropriate by considering the following requirements:

- involvement in the research carries no more than low risk to participants;
- the benefits from the research justify any risks of harm associated with not seeking consent;
- it is impracticable to obtain consent (for example, due to the quantity, age or accessibility of records);
- there is no known or likely reason for thinking that participants would not have consented if they had been asked;
- there is sufficient protection of their privacy;
- there is an adequate plan to protect the confidentiality of data;
- in case the results have significance for the participants' welfare there is, where practicable, a plan for making information arising from the research available to them (for example, via a disease-specific website or regional news media);
- the possibility of commercial exploitation of derivatives of the data or tissue will not deprive the participants of any financial benefits to which they would be entitled; and
- the waiver is not prohibited by state, federal or international law.

1.9 Sharing and Distribution of Biospecimens and Data

Metro South Health research projects must provide responsible custodianship of the biospecimens and data that they collect, maintain and share. Mechanisms must be in place to maintain the quality of biospecimens and data, protect participant privacy and confidentiality and to ensure that biospecimens are shared in a manner that is consistent with any consent obtained for the biospecimens.

Biospecimens and/or data should only be made available for ethical and scientifically appropriate research that is expected to contribute to scientific discovery. Please see Metro South Health Research Biorepositories - [Operational Arrangements Procedure \(PR2017/101\)](#) for more information.

Where it is intended for the research project to access data from the health data collections or from other collections for inclusion in the research project data the Principal Investigator must ensure participants are informed before consent is collected: what the health data collections are, and the possibility that the data collected by the research project and that obtained from the research may be linked with other data about the participant.

1.10 Termination of Research Projects

Metro South Health research projects must plan at the time of their establishment for the disposition of biospecimens and/or data should the research project be terminated for any reason. The disposition, including any transfer of biospecimens and/or data to third parties, must be consistent with the informed consent under which biospecimens and/or data were obtained. Please see Metro South Health Research Biorepositories - [Establishment of a Research Biorepository Procedure \(PR2017/100\)](#) and Metro South Health Research Biorepositories - [Disposal, Lab/Fridge Merge and Closure Procedure \(PR2017/105\)](#) for more information.

1.11 Ethical Disposal of Biospecimens

For some populations, disposal of biospecimens may have ethical considerations. Depending upon the nature of the study population and the research project, research biorepositories and recipient researchers may be required to dispose of unused biospecimens according to local, legal, ethical and safety rules for the disposal of human remains. Alternatively, recipient researchers may be requested to return unused biospecimens to the research project.

1.12 International Samples

On an international level, the collection and use of biospecimens is currently regulated by an amalgam of differing and occasionally conflicting laws and policies. Researchers must proceed carefully, not only in their daily work, but also with respect to international exchange of samples and associated data. Regulations in some countries address the ethical issues related to collections and use of biospecimens and to import and/or export of specimens as well as shipping regulations.

When obtaining samples of biospecimen from abroad, researchers must be satisfied they have been obtained in an ethical manner, in accordance with legislation and ethical standards. It is also important to respect the legislation and appropriate socio-cultural expectations of the country of origin. It is considered good practice to inform the participant during the consent process that their sample may be transported abroad for research, if this is known.

Metro South Health research projects SOPs for collection, storage, distribution, use and disposal of biospecimens and/or data must respect the perspectives and traditions of participants from whom the biospecimens were obtained and minimise the risks to communities, populations, and groups.

Metro South Health research projects that import biospecimens and data from other countries must respect the autonomy of the providing country and ensure that fair and equitable benefits are made available to the providing country. Please see Metro South Health Research Biorepositories - [Operational Arrangements Procedure \(PR2017/101\)](#) for further information.

In terms of governance, quality and safety, researchers should develop systems to ensure safe and appropriate transit of the sample e.g. sample tracking systems and risk management. Appropriate regulations and guidance for transport should also be followed. Please see Metro South Health Research Biorepositories - [Material Transfer Agreements, Packaging and Shipping Procedure \(PR2017/107\)](#) for more information.

2.0 Informed Consent

During the informed consent process, participants should have the opportunity to meet with a registered health practitioner and/or appropriately authorised/qualified scientific employee in order to discuss the nature and scope of the research project. Participants should also be provided with the opportunity to discuss with appointed designees and/or research project personnel. The Principal Investigator must ensure that such meetings are fair and neutral and do not, either directly or indirectly, create the potential for participants to feel pressure to participate in the research project.

The research project must ensure that potential participants are provided with reasonable time periods for providing their consent. The research project should always make clear to the potential participant that agreement or refusal to participate in the research project and its research will not affect medical care services that will be or could have been provided to them, nor prejudice or disadvantage them.

Informed consent for the collection, retention and use of biospecimens and/or data is a process that offers participants information sufficient to allow them to make an informed choice about whether to provide biospecimens and data to the research project and agree, where applicable, to future research use. Consent must only be obtained under circumstances that provide the prospective participant or the participant's representative sufficient opportunity to consider whether or not to participate and minimises the possibility of coercion or undue influence.

The information that is given to the participant or the representative must be understandable to the subject or their representative. During the informed consent process, the research project should provide potential participants with sufficient information on the nature, implications, foreseeable risks and benefits of their participation, so that they can realistically assess the implications of their participation and can make an informed decision on whether to participate. This information should be presented so as to not constitute an improper inducement to participate in the research.

2.1 Types of Consent

A Metro South Health uniform and consistent approach to participant information and consent processes not only supports consistent diagnostic practice and facilitates research, but also allows for the future use of biospecimens and/or data for quality and research purposes as well as storage for future diagnostic purposes.

Metro South Health research project personnel must be aware that there are personal sensitivities associated with the donation of tissue and be cognisant of this issue before approaching potential participants. Voluntary and informed consent is a key mechanism for protecting the rights of the participants. Consent encompasses the process that starts with initial contact and carries through to the end of the involvement of the participants in the research project. Consent may be obtained for a specific research project, such that the details of the project can be specifically outlined. Alternatively, consent may be obtained for unspecified future research (for which ethical approval will be sought), in which case general information about the possible future research uses are provided, in accordance with applicable national or local regulations and policies.

Mechanisms must be in place to assure that future research uses of biospecimens are consistent with the original consent (e.g. through review by a HREC or other mechanisms consistent with applicable regulations and guidelines). Participant consent must be obtained unless waived by an authorised HREC constituted in accordance with applicable laws or regulations. Consideration should be given to providing participants with graduated consent options to allow varying levels of involvement.

Consent should be recorded in writing when possible (and always when legally required). If the person giving consent is unable to write or is giving verbal consent, this should be clearly documented, including when consent was given and for what purposes. Consent should ideally be witnessed, normally by the researcher, signed by the witness and kept for future reference.

Further, as will be elaborated below, in view of the limited consent that can be obtained at the time that biospecimens and information are collected, research projects have an ongoing obligation to provide more information once it becomes available, for example, about who is accessing the resource and for what purposes.

2.2 Broad and Enduring Consent

During the informed consent process, the research project must provide potential participants with sufficient information on the nature, implications, foreseeable risks and benefits of their participation, so that they can realistically assess the implications of their participation and can make an informed decision on whether to participate. Whilst it may not be possible to know details of specific research projects, efforts should be made to describe the nature and purpose of the research as specifically as possible.

The amount of detailed information that can be provided to people when their consent is sought will vary depending on the nature of the collection: more specific information can be given in the case of a disease-based collection, where the research is disease-specific, compared with a research project established as a more general resource to study gene-environment interactions and the impact of genes on disease. In the latter case, it will be important to provide clear information on the nature and purpose of the research project.

When obtaining consent for use of samples in research, it is important to consider the potential value of those samples for future research. Metro South Health recommends that broad and enduring consent (also known as generic consent), that is consent which is broad in both scope and time, should be sought whenever possible. This allows for efficient use of samples, fosters trust with participants and avoids the need to either obtain further consent at a later date or to use samples without consent.

When seeking such broad and enduring consent, participants should be informed that samples may be used in future research, the nature of which may be unknown. A disease area may be specified or for medical research more generally.

If relevant, it should be made clear that possible future uses of the samples could include areas of research, which may be viewed as 'sensitive', e.g. where it may reveal clinically relevant findings, or there is the potential to identify participants.

Participants should be notified that any future research will conform to all relevant legal, governance and ethical requirements. This is an 'all or nothing' approach to consent, whereby participants agree that they understand the unknown aspects of future use, trust the governance procedures, and express a desire for their samples to be used for the maximal benefit of the research endeavour. If the participant has concerns about any aspect of future use, which cannot be addressed, then broad and enduring consent should not be used.

2.3 Two-part Consent

One way of managing broad and enduring consent is to adopt a two-part consent process. The participant is first asked to consent for the planned research, and then to consent for storage and future use of samples in other research, as above.

They should also be given the option of consenting only for the first part i.e. the planned project and not the second part, in which case provisions should be made to destroy the samples when no longer required for that purpose. When offering two-part consent, there must be adequate management systems in place to ensure that the participant's wishes can be met with respect to both the specific and broad and enduring elements.

2.4 Tiered Consent

Another possibility is to offer tiered consent, whereby the participant is able to consent to some, but not all, future uses of their sample e.g. some categories of research could be excluded. Where participants are offered graduated consent options these may cover issues such as:

- if the samples and/or data will be used for a single research study or for multiple studies;
- if the participant gives their permission to be re-contacted;
- options for the participant to withdraw samples and/or data from the research project;
- participant preferences for feedback;
- an option for the participant to choose if identifiable data can be accessed by researchers;
- options for participants to choose for their samples and/or data to be used for particular research areas;
- if or when the samples and/or data must be destroyed; and
- permission to transfer samples to another registered research project.

However, this approach is challenging to manage and requires robust systems that need to be maintained for as long as the sample is held in order to avoid the risk that the participant's wishes are not respected, no matter which consent preferences they select.

2.5 Withdrawal of Consent and/or Permission

Participants have the right to withdraw/revoke consent, either orally or in writing, to have their unused biospecimens and data removed from the research project unless the biospecimens and associated phenotypic or demographic data are anonymous and cannot be linked by the research project to participant identities.

Participants must be informed that they may exercise their right to withdraw without any explanation being required and that there will be no negative consequences for themselves or their family in regards to the provision of healthcare services.

The conditions under which a participant may make this request as well as the logistics for how a participant initiates this request must be specifically outlined in the informed consent document and documented process. If revocation of consent is received, either from the participant or guardian, prior to the removal of tissue, the registered health practitioner and/or appropriately authorised/qualified scientific employee must not remove the tissue from the participant.

Additionally, if the registered health practitioner and/or appropriately authorised/qualified scientific employee believes that consent contains a false statement then the consent is not considered sufficient authority.

Paediatric subjects and their parents or legal guardians must be informed that they are able to withdraw their assent or permission, respectively, at any point and decline to further participate in the process.

At the time of consenting, participants must be informed of the various options. In some situations, the right to withdraw may be restricted, and participants should be informed of this. If samples have been rendered non-identifiable or distributed, or if results are in the public domain or have been published, complete withdrawal may not be possible. Participants need to be informed about these situations. However, participants should also be reassured that complete confidentiality and protection of their samples and data will continue.

There are numerous options for a participant exercising their right of withdrawal. For example:

- no further contact - no further contact with the participant, but permits the continued retention and use of the previously obtained samples and data, and if applicable, linked to records from third parties;
- no further access - no further contact with the participant or access to health records but permits continued retention and use of the previously obtained samples and information; or
- no further use - no further contact with the participant, no further collection of samples or data, and destruction or rendering of all samples and associated data as non-identifiable. This may mean the research project is required to destroy the person's samples (although it may not be possible to trace all distributed sample remnants) and would hold information relating to the person only for archival audit purposes. The signed consent and withdrawal would be kept as a record of the person's wishes. Such a withdrawal would prevent information about the person from contributing to further analyses, but it would not be possible to remove data from completed analyses.

Details of information on withdrawal must be provided to participants prior to collecting informed consent. It should be clarified:

- if it is possible to withdraw samples, data or both;
- if they may withdraw at any stage;
- that there is no need to provide any explanation; and
- any consequences of withdrawal.

Where withdrawal is available to participants the Principal Investigator should ensure traceability of the samples and data is possible. Participants must be able to communicate their revocation of consent or agreement to the registered health practitioner who is attending the participant in a professional capacity, a nurse, appropriately authorised/qualified scientific employee, the research project manager and/or personnel or any other person employed at the Hospital. Contact details for revocation of consent must be included on the PICF.

2.6 Consent for Existing Collections

Throughout the lifespan of the research project, the research use of samples and data should be consistent with the original informed consent or new consent should be sought, except where otherwise provided by ethical guidelines, domestic law and consistent with state, national and international legal norms.

For a research project established from existing collections, the initiators or the Principal Investigator should consider whether the intended scope and purpose of the research project and intended research uses are consistent with the original informed consent.

Where they are not within the scope of the original informed consent, the samples and data may only be used if a new consent is obtained, except where exempt as per domestic guidelines and laws. The following principles guide Metro South Health research projects in consent issues relating to existing collections:

- There are historical collections held within Metro South Health research biorepositories. Consent for these collections may have been obtained for a single research project, for teaching, or for use as clinical assay controls. Alternatively, the consent may not meet the current standards for informed consent, or the parameters of consent may not have been adequately documented or consent may not have been obtained.
- Since obtaining consent retrospectively is often impossible or impractical, the ultimate use of these collections should be guided by the HREC. Therefore, research projects must ensure that the status of such collection is reviewed periodically (e.g. annually) by the HREC, and HREC approval to continue to maintain them must be obtained. Consideration should be given to their value, the parameters and conditions under which they were collected and the issues and difficulty involved in obtaining re-consent for such samples.
- Any new research projects that involve access to such collections should be reviewed by the HREC, as is the case for use of all research project materials. The researchers seeking access to these tissues should be made aware, if historical collections are provided, about the potential deviations, if any (or lack of information), from the currently established SOP. This information should be disclosed to researchers if the conditions of accrual and storage are documented.

2.7 Feedback

Consideration should be given to providing feedback to participants of aggregated results as a minimum. Where individual feedback is allowed, participants should be able to decide whether or not to receive feedback of individual results arising from research. If individual results are given to participants the Principal Investigator should ensure a trained professional gives this feedback or for counselling to be available to participants when this is appropriate.

The release of non-validated results (aggregated or individual) from research using the research project to participants is not recommended. If the researcher decides it is ethically necessary to release the results advice should be given to the participant about the difference between research and clinical results, clarifying the need for clinical testing of research results.

In certain circumstances, as permitted by applicable law and the appropriate authorities, where the participants may be provided with feedback of individual-level results arising from research, the research project should provide clear information to the participant of the consequences of receiving such results and should inform the participant of their right to opt out from receiving such results. Non-validated results from scientific research using a research project's biospecimens and data should not be reported back to the participants and this should be explained to them during the consent process.

2.8 Re-contact

Participants must be provided, at the time of consent with information about the conditions under which they will be re-contacted if applicable. This should include the circumstances under which they will be re-contacted, whether re-contact is obligatory for participation in the research project, and by whom they will be re-contacted.

Where re-contact to participants is available the Principal Investigator must ensure traceability of the samples and data is possible. Consistent with the terms of participation, participants should only be re-contacted through a representative or designee of the research project trained in dealing with sensitive issues and impartial in regards to the outcome of the research. If the research is likely to produce information relevant to the health and wellbeing of the person from whom the tissue was derived, processes to allow participants to be identified for follow-up should, where appropriate, must be included in the research proposal. The possibility of re-contact needs to be addressed in the information provided to prospective participants in the course of obtaining consent. A research project may wish to recontact participants for a number of reasons over the course of the research project's operation for various reasons including:

- to collect new information (such as questionnaire data, measures of samples) for the resource;
- to seek consent to proposed new uses that have passed scientific and ethics review but do not fall within the existing consent; and/or
- to ask participants whether they would be willing for researchers to contact them to discuss possible involvement in a study that requires new information or samples.

It must be emphasised that participation in all such assessments is entirely voluntary, and that any initial re-contact will be undertaken by the research project.

2.9 Re-consent

There are situations where, although a patient's/participant's consent was given at the start of participation, new consent needs to be considered (there will also be circumstances where a research project holds biospecimens obtained without specific participant consent); see [Section 1.8 Waiver](#) of consent. It may also be necessary to obtain fresh consent from participants if there are major changes to the research project. However, even where broad consent is obtained for prospective research projects, there may be circumstances in which there has been a major modification to the research direction for the research project such that it is of a fundamentally different nature to that initially proposed. In these circumstances, it may be appropriate to seek re-consent from participants or, where that is not possible, to seek waiver of consent from a HREC.

3.0 Ethical Considerations Specific to Participants

Metro South Health research projects must ensure careful consideration is given to any special issues related to the participation of vulnerable populations or groups, including children, individuals with impaired decision-making capacity, and prisoners. For research relating to a large portion of a population (e.g. looking at the correlation between a specific heritage and a specific disease) the initiators and the research project Principal Investigator must give consideration to the potential for discrimination not only for participants but also for individuals, families and groups who have not participated. For example it should be disclosed that individual and population-based genetic data may have repercussions for a participant, his/her family, a group he/she is part of and his/her community as a whole. It should be disclosed where these repercussions may include insurance or employment difficulties or a loss of dignity.

Where substitute consent has been obtained for a participant lacking capacity (e.g. a minor or individual with impaired decision-making capacity), consideration will need to be given to what will occur once the participant gains or re-gains capacity to consent. In accordance with applicable law and ethical principles, consent may need to be obtained from the participant to continue in the research or to collect further data or biospecimens from them or their withdrawal of consent. For example, particular consideration may be needed in situations where a minor has been recruited as part of family studies. Please see [Specific Human and Animal Ethical and Scientific Review Requirements Procedure \(PR2017/114\)](#) for more information.

3.1 Biospecimens to be Used for Genetic Analyses

Metro South Health must not conduct tests for genetic conditions, or potential disease traits in individuals or their offspring, without the free, informed and voluntary consent of the individuals to be tested.

Some research projects either use a “tiered consent” form (one that allows participants to consent to some aspects of the research but not others) or require a separate consent form to be signed by participants when their biospecimens may be used for genetic testing or for mutation analysis. When genetic information generated from biospecimens is stored in a database, it is important that confidentiality is maintained and that the database server is secure.

Complex ethical issues arise when genetic testing is performed on biospecimens, such as whether to inform participants of their research results, whether to inform participants’ families when heritable genetic factors are identified in tissues, especially post-mortem tissues, whether to inform families about possible disease risks, whether to ask relatives to collaborate on heritable genetic testing, and whether to advise relatives to seek genetic counselling.

These ethical issues are currently unresolved and are especially difficult if there is no known treatment or cure for the disease at hand. Furthermore, in some jurisdictions there are laws that prohibit the return of results unless conducted in an approved laboratory. Even then, the results or their interpretation may be incorrect and their use in medical decisions might cause harm to participants. Thus, it is essential to discuss these issues with the HREC during the design of a Research Protocol and informed consent and before returning any research results to subjects, their families or physicians.

The ability to study samples stored in research biorepositories and to generate information about genetic disease and susceptibility to disease has raised concerns over risk to participants associated with discrimination and stigmatisation of individuals. Privacy of research results should never be breached, as the consequences for the participant are likely to be social, economic and psychological.

Much genetic information generated as results from research is of unknown or uncertain predictive value. Results should never be disclosed to the participant or added to medical records unless consent is obtained through a HREC approved Research Protocol. If consent is sought, then appropriate counselling must be available. Metro South Health must provide appropriate counselling and support to individuals prior to and after genetic testing to assist individuals to decide whether they wish to undergo genetic testing and help them assess and managed the results of genetic tests.

During this counselling, participants should be advised of the potential risks and implications of genetic information (e.g. on family members, relationships, employment and insurance). Research projects must respect the right of each individual to decide whether or not to be informed of the results of genetic testing, and the resulting consequences will be respected. Counselling will address the limitations of genetic testing as well as the potential benefits.

Participants must be advised that genetic testing does not, in all circumstances, provide certainty that the person tested or their offspring will develop particular diseases (conditions may be linked to multiple rather than single genes; environmental factors may also play a significant or dominant role in whether particular people develop diseases for which they may have genetic susceptibility).

3.2 Gametes, Foetal Material and Embryos

The legal requirements for the use of gametes and embryos in research differ from other forms of biospecimen. Researchers should be aware of the requirements and specific sensitivities in use of these materials before undertaking such research.

3.3 Age Considerations

Some research projects have decided not to include children however some research projects may for practical reasons seek to recruit the children of parents who have been research project participants, once those children reach adulthood.

For research projects that plan to include children whilst they are still minors, there are important issues in relation to consent to be addressed. In particular, involving children as research project participants entails deciding what constitutes appropriate consent for their participation: whether it be consent from the parent, the child or a combination of both.

Until the subject in question is of legal age, parental or guardian permission is required for the paediatric subject to participate in research. The question, however, of when to progress from using a paediatric assent document to using an informed consent document is less clear and tends to be institution and/or HREC dependent.

The process and documentation must be designed with the emotional, developmental and cognitive abilities of the paediatric population in question. If the paediatric subjects are adolescents, it may be possible to use the same documentation as is used to secure informed consent from adult participants, with the caveat that parental permission is still required as a necessary first step. A new consent may be required from the participant once he/she reaches the age of majority.

Metro South Health research projects must consult with a HREC for guidance on whether subjects that have reached the age of majority should be re-consented or whether a waiver of informed consent by the HREC is appropriate.

3.4 Special Considerations for Collection of Children and Young People Biospecimens - Enrolment of Subjects

The collection, storage and distribution of biospecimens from paediatric subjects create additional ethical considerations, particularly in the areas associated with the gathering of informed consent from subjects. All elements described above associated with the use of samples from adult subjects should also be adhered to when working with paediatric subjects, including securing HREC approval for all processes and procedures, the minimisation of risk associated with subject participation including the risks associated with the loss of privacy and confidentiality, and the termination of specimen resources. The age of paediatric participants may be critical and require more detailed documentation (e.g. days, months, years). Policies and legal requirements may differ by country and region if receiving samples internationally.

3.5 Parental Permission and Paediatric Assent

Subjects below a certain age are not able to provide informed consent. Instead, parental permission and paediatric subject assent (in cases where assent may be given), is obtained in lieu of informed consent.

Assent must include helping the participant understand the nature of their condition, informing them of what they can expect with tests and treatment(s) and obtaining an expression of the patient's willingness to accept the proposed care.

The documentation associated with obtaining parental permission is similar in nature and content to a document used to obtain informed consent from an adult with the exception that the documentation contains references to the minor child as the participant.

The components of the parental permission documentation must include a complete and understandable description of the procedures associated with the collection, storage, and distribution of the biospecimens, risks and benefits (if any), options other than participating, and opportunities to withdraw permission.

The process of securing parental permission must include the opportunity for the parent or guardian to discuss and question the paediatric participant's potential involvement in the research until a level of full understanding is reached.

Once parental permission is obtained, the process of securing paediatric assent may be undertaken if the participant in question is at an age and developmental level where assent may be given. The assent process must be conducted through the discussion of the research, procedures, and processes with the child in age appropriate language, including the opportunity for the child to ask questions.

As with the securing of adult permission, key topics must be covered with the child, including the facts that they do not have to participate and that they may withdraw their assent to participate at any time in the future. For children who are either not yet old enough to read or not able to read, this assent process may be conducted orally, assuming that the appropriate HREC has approved the enrolment of children of that age.

For children of reading age and ability, a paediatric assent document should be utilised. Assent documentation should be drafted in language that is age appropriate, easily understood, and likely to encourage questions and discussion. As with the process to obtain informed consent and parental permission, the process associated with obtaining paediatric assent should be an interactive process where information is freely shared and decisions are made in an informed fashion.

3.6 Biospecimens Obtained from Mentally Impaired Persons

Extra care and attention must be given to the consent process when participants are incapable of signing the consent form themselves. Participants in this group would include those under heavy sedation, patients with dementia, or patients with syndromes of impaired consciousness, such as coma, brain death, locked in syndrome, and persistent vegetative state.

Ethical guidelines for the management of participants in these conditions are included in the National Statement. In cases of demented or mentally incompetent participants, a relative or legally authorised person could sign the consent form on the participant's behalf. In some countries, the participant must be informed regardless of their age, medical, or mental condition.

The Principal Investigator should also ensure consideration is given to whether the mental capacity of the participant will be reassessed during any re-contact with the participant and/or what the effect of a participant being found to lack capacity on re-contact will be (e.g. further data or samples may not be lawfully collected thereafter, and whether the fact of their incapacity will be recorded and included in the research database). Where substitute consent has been obtained from a participant lacking capacity (e.g. a child), and new consent is to be collected particular care will need to be given to respecting the individual privacy of each participant where children have been recruited into family studies.

3.7 Consideration of Perspectives of Communities, Populations, Ethnic and Social Groups

In some cases, there may be risks to ethnic and social groups or communities due to the release of aggregate research findings even when no individually identifiable information has been revealed. In addition, some populations or groups have specific beliefs about the disposition and use of their biospecimens, which should be respected.

When research focuses on a particular community it is best to seek input from representatives of the group on relevant aspects of the design of the research project, the consent process, appropriate uses of biospecimens and dissemination of collective research findings.

Considerations must be given to the needs of participants especially for those who are less educated, elderly, or who are not native speakers. Where relevant, for the potential participants, the information should be translated into their native language/mother tongue.

The information provided as part of the recruitment process should take into consideration the patient's/participant's cultural and/or religious beliefs. The Principal Investigator should ensure consideration is given to the need for certain cultures to make decisions on participation at a community or group level, in addition to, an individual level.

The SOPs should allow consent to be collected both ways as necessary. Additionally, Principal Investigators must also ensure that its SOPs on procurement, collection, labelling, registration, processing, storage, tracking, retrieval, transfer, and use of biospecimen and data take into consideration cultural heritage and/or religious beliefs known or disclosed by participants and/or their representative groups.

3.8 Communication Strategies

Consideration must be given to employing different communication strategies, formats and modes for providing information to participants during the informed consent process and during the lifespan of the research project. Where appropriate, participants should be provided with the opportunity to communicate with representatives of the research project, or as required designees. Communication strategies should take into consideration the different needs of the participants and that consideration should be given to employing different formats and modes for providing information to participants.

One way in which to facilitate the consent process and help the participant make an appropriately informed decision is by providing an information sheet. This must be presented in a form that can be easily understood. Metro South Health has provided guidance on preparing PICFs, please see Attachment [2](#) and [3](#). Researchers must be aware that members of some ethnic or religious groups might find some types of research, or donation of certain types of human material, unacceptable, which will influence the sensitivity of approach.

When providing information various methods to provide information should be considered, whether during the consent process or to provide information to the public. Efforts should be made to employ the most environmentally-sound and cost-efficient means of communications.

Information and feedback of results to participants may be provided in different forms and in more than one form including: the publication of results, leaflets; annual reports; information sessions; newsletters; meetings with counsellors; television; radio; newspapers; internet blog sites or websites which may hold summaries of research findings and lists of publications.

Decisions on the communications approaches to be employed should take into account the diversity of the targeted audience. Consideration should be given to technology issues (i.e. paper versions of the documents should be made available especially for those who are not familiar with technology),

language issues (i.e. do the documents need to be translated into a language of a large segment of the population, even if it is not an official language) and diverse challenges (i.e. information may be more accessible for a portion of a population if it is made available in video format, and it may be more accessible for the visually impaired if converted into Braille script). Communication strategies should also take into account the consent process for children.

While it is recognised that for certain research projects it may not be possible for some information provided during the consent process to be made publicly available (e.g. protected or proprietary information) it should always be provided to potential participants.

If, during the informed consent process, participants meet with staff from the research project, the Principal Investigator must ensure the meetings are fair and neutral and do not, either directly or indirectly, create the potential for participants to feel pressure to participate in the research project. Additionally, the Principal Investigator should ensure that potential participants are not placed under rushed time constraints for providing consent.

Whilst consent is generally obtained in writing, there may be circumstances where verbal consent would be acceptable; for example, if the person is illiterate or cannot write. In such circumstances, the process by which non-written consent is obtained needs to be recorded.

3.9 Incapacitation or Death

As the beliefs of the participant may not be known to the researcher, due sensitivity should always be shown when approaching relatives to ask for consent. Since consent is being sought at a particularly stressful time, relatives should wherever possible, be given time to reflect before making their decision, and it is particularly important that written information is provided for later reference. In some cases, the balance between the wishes of a deceased participant and those of the relatives may be difficult to reach i.e. the relatives object to the donation despite consent from the deceased before death.

In situations where it is known that a potential participant's illness is terminal, a relationship can be established between the participant, their relatives and the research team before they die. This aids the communication of the wishes of the participant to their family and the researchers. The research team may wish to seek permission from the next of kin to be contacted after the death of the potential participant to inform them about donation and research. There are a number of ways to approach what should happen when a participant becomes incapacitated or dies. For example:

- participants could be informed their samples and data will remain with the research project;
- participants could be offered the option for a legal representative to withdraw the participant; or
- participants could be informed their samples and data will be made non-identifiable following notification of their death.

In terms of confidentiality, identifiable participant information about a deceased person should continue to be treated as confidential.

3.10 Biospecimens Obtained from Autopsies

Biospecimens may also be obtained during autopsy from pathologists at hospitals, institutions, or the coroner's office. Full consent or authorisation must be obtained from the participant (e.g. a signed agreement to donate their body for scientific research), the next of kin, or a legally authorised person. It is important to rapidly harvest organs and tissues soon after the person has deceased (i.e. a "rapid autopsy"), since mRNA and many proteins are sensitive to enzymatic degradation.

There are some ethical and legal considerations specific to the use of biospecimen from the deceased, consent/authorisation being a fundamental principle. It is important that researchers respect any individual, religious or cultural beliefs which may be pertinent when dealing with donations from a deceased person.

A registered health practitioner and/or appropriately authorised/qualified scientific employee may, by signed writing, authorise the removal of tissue from the body of a deceased person under the consent if the:

- body of the deceased person is in a hospital;
- it appears to a registered health practitioner, after making reasonable enquiries, that the deceased person had not, during her or her lifetime, expressed an objection to the removal after death of tissue from his or her body; and
- the senior available next of kin has consented to the removal of tissue from the body for storage and/or scientific purposes and disclosure of the deceased person's health record.

Any consent documents must be placed on the deceased person's hospital record as soon as practicable.

3.11 Biospecimen Collected from Colleagues

The same legal and ethical standards apply to obtaining samples of biospecimen from colleagues as would to any other participant in research. Valid and freely given consent must be obtained from colleagues. This includes giving information on what samples will be used for, the risks of discovery of health related findings and how these would be handled, how their privacy will be protected and their right to withdraw.

Particular attention must be given to the following when asking colleagues to donate samples:

- the possibility of a perceived obligation to participate and the anxiety that colleagues may feel of not wanting to appear obstructive or difficult;
- ensuring privacy of research results; and
- uncovering health related findings in situations where participants are likely to be known by those working on their samples.

All requests for donations and consent procedures must be conducted by those who do not have a direct managerial or supervisory role with those being asked to donate. Potential participants should be given the opportunity to ask questions about the research from a person independent of their immediate colleagues if possible. Independent ethical oversight of research involving colleagues is required. This should be in the form of a positive opinion from a HREC.

3.12 Ethical Collection of Animal Biospecimens for Research

Scientific researchers who work with animal models generally agree that experiments that follow the best animal welfare procedures result in the best science. Three Rs (reduction, refinement and replacement) in animal procedures should be an integral part of any research project, to help minimise animal use and suffering and to facilitate good scientific practice.

The refinement of scientific procedures carried out on animals to minimise adverse effects and to maximise the scientific benefit gained is a legal and ethical requirements. Nevertheless, refinements are not always implemented for a variety of reasons. The 'five freedoms' concept can be taken as general indicators of laboratory animal welfare.

These five freedoms are:

- 1) freedom from injury and disease;
- 2) freedom from discomfort, hunger and thirst;
- 3) freedom from pain;
- 4) freedom to express normal behaviours; and
- 5) freedom from fear and distress.

In any animal resources facility, researchers must implement actions to minimise the impact of the procedures they perform on these five freedoms. Currently, animals are sacrificed in laboratories or breeding establishments for a variety of reasons including:

- when animals have passed the age of being suitable for breeding;
- to provide blood and other tissues samples for a scientific analysis;
- at the completion of an experiment or due to continuing adverse effects;
- to end an experiment because the levels of pain, distress and suffering are likely to exceed a certain level;
- in situations where the health or welfare of the animals are a matter of concern; and
- to eliminate animals with improper characteristics such as type or sex.

In terms of animal welfare, the primary criteria for euthanasia should follow the rules: the method should be painless, achieve rapid unconsciousness and death, require minimum restraint, avoid excitement, should be suitable for the age, species, and health of the animal, must minimise fear and psychological stress in the animal, should be reliable, reproducible, irreversible, simple to administer (in small doses if possible) and safe for the operator.

The use of carbon dioxide (CO²) for the sacrifice of mice and rats is widely accepted because of its low cost and easiness. However, the use of CO² has been recently contested and additional measures, such as anaesthetising the animal to avoid panic or pain or performing cervical dislocation to ensure that gassed mice are dead, are being proposed.

The limitation of the number of animals for experimental procedures might be disadvantageous, since strategies that reduce the numbers might produce a disproportionate increase in the pain and distress caused to the animals that are included in the experiments. Therefore, researchers should think in terms of minimising, rather than reducing, the numbers of animals used.

Through the harmonisation of procedures among animal resource centres it is expected that minimisation/elimination of pre-analytical confounding variables and the resulting comparability of studies will result in a reduced number of animals used for experimental research. Such harmonisation will result in better animal welfare standards in a way that both animals and science benefit from harmonisation.

3.13 Collection Permits for Wildlife Samples

Collecting wild organisms is controlled by international directives and national laws. Failure to heed these laws can be damaging for biodiversity and can circumvent fair access and benefit sharing among countries. It should be checked before leaving on a field trip which permits are needed.

5.0 Participant Information and Consent Form

Appropriate consent is based on the principle that competent individuals are entitled to choose freely whether to participate in research and should be given appropriate information to be able to make this choice. Participants asked to consent to donation should be properly informed, have capacity to make the decision to participate under no coercion or pressure, and understand the right to withdraw from the research at any time without giving a reason, and in the case of patients, without their future medical care being affected.

Information should include the process involved in obtaining samples, any significant associated risks, and if known, what the samples will be used for and how the results of the research might impact on their interests. Participants must be informed of intentions for future storage and use of samples, including the possible sharing of samples with others. Participants should be given time to consider the information provided before being asked to sign the consent document. Participants should also be provided with a copy of their signed consent document, where applicable.

The informed consent materials should be written in clear, concise and simple language that is easy to understand by the participant. Information provided to participants during the informed consent process should be presented in a way so as not to constitute an improper inducement to participate in the research.

Prior to requesting signed consent the Principal Investigator must ensure potential participants are provided with information including (refer to the specific section for further details on these recommendations):

Set-up and management

- background information behind, and the purpose of the research project;
- the ethical and governance framework and management responsibilities;
- if the research project has been or is being established in collaboration with the private sector or if it is involved in collaboration for commercial purposes;
- the nominated Principal Investigator of the research project;
- the purposes for which the data will be used and/or disclosed;
- any conditions where the nominated Principal Investigator may change;
- storage facilities and duration of storage;
- any legal or intellectual property rights that might be material to their participation;
- clarification of ownership issues with respect to the biospecimens, information and the collection;
- SOPs governing the collection, storage, use and outcomes from research on samples and data and/or details of how participants can obtain further information on the policies;
- sample or data transfer and disposal/destruction processes;
- the samples and data to be collected, and which samples and data will be collected from the participants or from other sources;
- if identifiable samples and/or data will be stored, the circumstances where it may be released and if samples and/or data may be released interstate or internationally;
- the duration of storage, transfer and disposal procedures, including, for international transfer of data where applicable;
- whether third parties may be given access to samples or data and the conditions under which

this will occur such as insurers, employers or law enforcement agencies or for public health emergencies;

- the conditions under which law enforcement agencies may access samples and/or data and any legislation that may apply;
- the level of privacy and confidentiality protection to which their samples and data will be subject, the procedures and safeguards that will be employed for this protection, and of any specific risks of unauthorised access;
- of any commercialisation that will result from the research performed on the research project, the conditions of this commercialisation and how this applies to the participants;
- if the research project closes, the manner in which the samples and data will be destroyed or transferred and what will be done with the research project assets;
- the possibility of sharing biospecimens and data with commercial entities, including those from other countries, and the publication of data and its availability on the internet;
- the process with respect to the sharing of benefits from the research;

Nature of Consent

- the nature of the consent that is being sought (whether it is specific, extended or unspecified) (National Statement, paragraph 2.2.14);
- circumstances in which re-consent might need to be sought and/or in which a waiver of consent may be sought;
- communication strategies and whether participants will be re-contacted in the future, the circumstances in which re-contact will be permitted and the conditions that will govern re-contact;
- whether information from or about family members, in addition to that provided by participants, is required for the research;
- whether child participants will be involved and whether, when and how a child's assent will be obtained;

Implications for participation

- the nature of participating and the implications;
- any foreseeable risks and benefits of their participation to themselves, their blood relatives and their community;
- where to find further information including details for contacting the Principal Investigator;
- if participants are entitled to withdraw from the research, conditions of withdrawal and consequences;
- if feedback of results to the participants will occur and the type of results included;
- if the participant will be re-contacted and the conditions of re-contact;
- the risk of psychosocial harms such as potential stigmatisation or interfamilial conflict, and the possibility that research may create or augment the risk of stigmatisation or discrimination of groups;
- whether the research may reveal information of potential importance to the future health of participants or their blood relatives;
- whether or not individual or aggregate research results will be released to the participant and/or his or her family or health care provider;

- arrangements for the biospecimens and data in the event of incapacity or death of the participant;
- proposed arrangements in the event of the discontinuation of the research project;

Withdrawal

- the right to withdraw, the available types of withdrawal, the implications of such withdrawal, and whether it will be possible to withdraw biospecimens and data;
- the research participant's absolute right to withdraw consent;
- how this right is to be exercised (including relevant contact details);
- what will happen if this occurs (including what is to happen with any remaining biospecimens);
- the limitations on withdrawal if the person's biospecimen and data have already been distributed;

Access and use

- the intended uses of the research project (including if it is to be used for non-research purposes e.g. quality assurance and proficiency testing);
- the terms and conditions of access to the research project samples and data;
- if specific types of tests are not allowed to be performed on research project samples or if specific types of data will not be recorded;
- data linkage, health and other records to be accessed and/or their intended uses (where the Principal Investigator intends to access data for inclusion in the research project from health or other records, which data will be extracted from such records, by whom and through which processes, and for which uses the data will be employed);
- if the data collected, and that obtained from the research will be linked with health data collections or other data collections;
- the form in which the data will be stored (identifiable, re-identifiable, non-identifiable) but noting that genetic material is in principle re-identifiable, even if identifiers are removed;
- the policy with regard to access to biospecimens and data by third parties such as insurers, employers or law enforcement agencies;
- information for contacting the research project; and
- mechanisms in place for ethical oversight of the research, including, where relevant, details of the governance model of the research project.

Please see [Attachment 3](#) for a detailed Patient Information and Compliance Tool which details items which must be included in a Metro South Health PDCF. Principal Investigators may utilise this document to ensure they are compliant with all principles outlined in the National Statement.

5.1 Metro South Health Broad and Enduring Consent

Metro South Health research projects may opt to utilise the Metro South Health PDCF Template as opposed to developing a project specific material. Principal Investigators are able to fill in specific details relevant to their collection. Please see [Attachment 2](#) Metro South Health Participant Information and Consent Form Template.

5.2 SOPs

The Principal Investigator must ensure there are SOPs in place on participation that include:

- the effects, if any, of the patient's/participant's death or loss of legal capacity;

- feedback that will be provided to participants and if individual results and/or aggregate results will be provided;
- whether participants will be re-contacted during the course of the research project's existence, the situations for which re-contact will be permitted, and the conditions that will govern re-contact (the process should ensure any re-contact permitted is not unduly burdensome for participants);
- whether researchers using its database(s) will be allowed to contact participants directly;
- whether, when and how a child's assent will be obtained and including what steps, if any, will be taken once the child becomes legally competent to consent;
- whether autopsy material will be collected, what will be collected and under what circumstances this will be carried out, and that the necessary legislative requirements are complied with; and
- if samples and data will be made available for analyses developed from technological advancements made since the original consent was collected particularly if these analyses are not covered by the original consent.

SOPs may also be implemented instructing personnel to not perform specific tests, this could include things such as paternity testing, HIV/AIDS testing or testing for the use of illicit substances.