

## PROCEDURE

# Research Management - Specific Human and Animal Ethical and Scientific Review Requirements

PR2017/114  
Version No. 1.0

### PURPOSE

---

Certain human research projects must satisfy specific ethical and scientific review requirements in addition to review by a local or lead Human Research Ethics Committee (HREC), before they take place in Metro South Health. The purpose of this Procedure is to ensure that all specific human and animal research conducted within or supported by Metro South Health complies with National Health and Medical Research Council (NHMRC) guidelines relating to medical and health research.

### 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 within or in association 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 in establishing appropriate specific human and animal ethical and scientific review processes:

- Appropriate consumer involvement in research is encouraged and facilitated by Metro South Health and must be undertaken in accordance with the NHMRC Statement on Consumer and Community Participation in Health and Medical Research.
- All activities involving gene technology, including Genetically Modified Organisms (GMO), and high-risk biological agents and materials must undergo scientific review, approval and monitoring by an appropriate Institutional Biosafety Committee (IBC).
- If required, research which involves working with children under the age of eighteen (18) and falls into one of the specified categories requires a Working with Children Check.

- Researchers must conduct their research so as to minimise adverse effects on the wider community and the environment.
- Metro South Health facilities involved in animal research as defined by the NHMRC Guidelines for Promote the Wellbeing of Animals Used for Scientific Purposes 2008, are required to ensure that all research on animals conforms to the Commonwealth, National and State guidelines, policies and legislation relating to the ethical conduct of animal research.
- Activities involving the use of animals for scientific purposes (research and teaching) must undergo ethical and scientific review, approval and monitoring by an Animal Ethics Committees (AEC).
- Facilities lacking Animal Ethics Committees (AEC), but undertaking animal research, must have an agreement with an external organisation to have access to a registered Animal Ethics Committees (AEC).
- All research must comply with the regulatory requirements for animal research as set by the relevant Animal Ethics Committees (AEC) or collaborating organisation (e.g. Universities/Research Institutions).
- Researchers will respect the animals they use in research, in accordance with the Australian Code of Practice for the Care and Use of Animals for Scientific Purposes and *Animal Care and Protection Act 2001 (QLD)*.

## LEGISLATION OR OTHER AUTHORITY

---

### Legislation

- *Coroners Act 2003 (Qld)*
- *Defence Trade Controls Act 2012 (Cth)*
- *Gene Technology (Queensland) Act 2016 (Qld)*
- *Gene Technology Act 2000 (Cth)*
- *Guardianship and Administration Act 2000 (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)*

### Regulations and Standards

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

### Statements, Papers and Guidelines

- National Health and Medical Research Council (NHMRC):
  - [Australian Code for the Care and Use of Animals for Scientific Purposes 8<sup>th</sup> Edition 2013](#)
  - [Australian Code for the Responsible Conduct of Research 2007](#)
  - [Guidance: Safety monitoring and reporting in clinical trials involving therapeutic goods](#)
  - [Guidelines to Promote the Wellbeing of Animals Used for Scientific Purposes 2008](#)
  - [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](#)

- [Statement on Consumer and Community Involvement in Health and Medical Research \(2016\)](#)
- [Values and Ethics - Guidelines for Ethical Conduct in Aboriginal and Torres Strait Islander Health Research 2003](#)
- 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](#)
  - [Standard Operating Procedures for Queensland Health HREC Administrators 2013](#)
  - [Standard Operating Procedures for Queensland Health Research Governance Officers 2013](#)
- Therapeutic Goods Administration: [Note for Guidance on Good Clinical Practice \(CPMP/ICH/135/95\) 2000 - Annotated with TGA Comments](#)

## RESPONSIBILITIES

---

### **Executive Management Team**

Ensure collaborative, harmonised, clear and detailed publicly available Policies and Procedures are in place for the ethical and scientific review of all Metro South Health research.

### **Metro South Health Human Research Ethics Committee (HREC)**

Provide oversight of the scientific and ethical review of Metro South Health human research by keeping abreast of international, national and state-wide legislation, regulations and guidelines. Promote Metro South Health strategic requirements and ethical and responsible decision-making which respects the rights of Metro South Health participants.

Ensure specific human and animal research projects have been ethically and scientifically reviewed by an appropriate body e.g. Institutional Biosafety Committee (IBC) or Animal Ethics Committee (AEC).

### **Centres for Health Research**

Update Metro South Health ethical and scientific review documents in accordance with Metro South Health HREC requirements. Provision of secretariat/administrative support to maintain and uphold principles outlined in the [Metro South Health Research Management Policy](#) and related Procedures.

### **Researchers**

Adhere to all relevant Policies, Procedures, Research Protocols and Standard Operating Procedures (SOPs) when conducting research.

### **All Metro South Health Employees**

Are required to be aware of and comply with this Procedure when conducting research.

## SUPPORTING DOCUMENTS

---

### **Attachments**

Attachment 1 - [Application](#)

## Forms

[Public Health Act – Application and Information for Researchers](#)

## DEFINITIONS

---

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

## PROCEDURE - SPECIFIC HUMAN AND ANIMAL ETHICAL AND SCIENTIFIC REVIEW REQUIREMENTS

---

### Step 1: Establish the Research Question

Establishing a research question requires rigorous review of literature to ensure there is an unmet need within healthcare delivery. When developing a research question it is important to ascertain if specific human and animal ethical and scientific review will be required in addition to Human Research Ethics Committee (HREC) approval. This includes research pertaining to:

- gene technologies and related therapies;
- ionising radiation;
- use of approved and unapproved medicines and medical devices;
- access to coronial material for research purposes;
- research involving adults with impaired capacity to consent;
- research involving persons in custody and/or employees of Department of Justice and Attorney-General;
- research that may affect the health and wellbeing of Aboriginal people and communities;
- research requiring access to state-wide data collections;
- clinical trials with persons unable to provide consent; and/or
- use of animals.

Please see [Biospecimen Ethics and Participant Information and Consent Form Procedure \(PR2017/115\)](#) for more information.

### Step 2: Identify Requirements

Metro South Health only operates a HREC which reviews the ethical and scientific validity of proposed human research within the Health Service and gives ethical approval to medical research projects.

Research projects which involve Metro South Health participants, data and/or resources as well as specific human and animal research must be reviewed by **both** the Metro South Health HREC and appropriate reviewing body.

### Step 3: Submit Research Protocol to Specific Human and Animal Research Review Committee

If a research project requires specific human and animal research review the Principal Investigator is responsible for identifying an appropriate reviewing body. To assist researchers in this process the below table identifies relevant review bodies which pertain to specific ethical and scientific review requirements:

|  |   |   |
|--|---|---|
| Gene Technologies and Related Therapies  | <a href="#">Queensland Clinical Trials Network</a><br><a href="#">UQ Institutional Biosafety Committee (UQ IBC)</a> | Prior to Metro South Health HREC Review     |
| Ionising Radiation   | <a href="#">Queensland Health Radiation Safety Unit</a>   | Prior to Metro South Health HREC Review     |
| Use of Approved and Unapproved Medicines and Medical Devices                                     | <a href="#">Therapeutic Goods Administration (TGA)</a>  | N/A   |
| Access to Coronial Material for Research Purposes  | <a href="#">Queensland Health Forensic and Scientific Services Human Research Ethics Committee (FSS-HREC)</a>       | Metro South Health HREC Review Not Required |
| Research Involving Adults with Impaired Capacity or Unable to Consent                            | <a href="#">Queensland Civil and Administrative Tribunal (QCAT)</a>   | Post Metro South Health HREC Review         |
| Research Involving Persons in Custody and/or Staff of Department of Justice and Attorney-General | Queensland Department of Justice HREC   | Parallel to Metro South Health HREC Review  |
| Research that May Affect the Health and Wellbeing of Aboriginal People and Communities           | <a href="#">Aboriginal Health and Medical Research Council (AH&amp;MRC) Ethics Committee</a>                        | Prior to Metro South Health HREC Review     |
| Research Requiring Access to State-wide Data Collections   | Queensland Population and Health Services Research HREC<br><a href="#">Queensland Central Cancer Registry</a>       | Prior to Metro South Health HREC Review     |
| Animal Research  | <a href="#">UQ's Animal Ethics Committees</a>   | Prior to Metro South Health HREC Review     |

### Step 5: Metro South Health HREC Office/r

Researchers must contact the Metro South Health HREC Office/r via telephone (07) 3443 8049 or email [EthicsResearch.PAH@health.qld.gov.au](mailto:EthicsResearch.PAH@health.qld.gov.au) to discuss the proposed research project. Proceed with steps identified in [Biospecimen Ethics and Participant Information and Consent Form Procedure \(PR2017/115\)](#) (if required).

## PROCEDURE DETAILS

---

**Procedure Number**

PR2017/114

**Procedure Name**

Metro South Health Research Management -  
Specific Human and Animal Ethical and  
Scientific Review Requirements Procedure

**Policy Reference**

PL2017/55

Metro South Health Research Management  
Policy

**Supersedes**

Nil

**Procedure Author**

Erica Davies, Project Manager, Research  
Development, Centres for Health Research,  
Metro South Health

**Portfolio Executive Director**

Professor Ken Ho, Chair, Centres for Health  
Research, Metro South Health

**Approving Officer**

Dr Stephen Ayre, Executive Director, PAH-QEII  
Health Network, Metro South Health

**Approving Date**

30 June 2017

**Effective From**

30 June 2017

**Date of Last Review**

30 June 2017

**Date of Next Review**

30 June 2020

### 1.0 Specific Human Ethical and Scientific Review Requirements

In addition to the ethical considerations pertaining to all human research participants, specific issues arise in the design, conduct and ethical review of research involving specific categories of participants. The impact of research on wider populations is an important ethical consideration in the design, review and conduct of human research.

Whilst ethical review by an accredited HREC is required for any human research additional ethical and scientific review may also be required dependent on the research project. Where other guidelines and codes of practice in particular research fields are consistent with the National Statement, researchers and members of ethical review bodies should draw on them when necessary to clarify researchers' ethical obligations in particular contexts.

#### 1.1 Regulation of Gene Technologies and Related Therapies

Metro South Health researchers are required by law to abide by the Commonwealth scheme for the regulation of Genetically Modified Organisms (GMOs) in Australia as defined in the *Gene Technology Act 2000 (Cth)* and the Gene Technology Regulations 2001.

Metro South Health facilities in which researchers are using gene technology or undertaking dealings (as defined in the legislation) must be accredited and maintained, or have an established link with, a properly constituted Institutional Biosafety Committee (IBC) within a collaborating organisation.

The research should be assessed and comply with recommendations made by the NHMRC Cellular Therapies Advisory Committee (CTAC), and the Institutional Biosafety Committee (IBC) prior to review and approval from a HREC.

Before approving a gene therapy proposal, a HREC should submit the proposal to the NHMRC's Gene and Related Therapies Research Advisory Panel for comment on its medical scientific, ethical and safety aspects. All research projects involving gene therapy and related gene technologies including xenotransplantation must be submitted to a HREC for review.

#### 1.2 Ionising Radiation

All research involving any form of radiation must comply with the relevant national and state legislation, codes and standards of practice as listed by the NHMRC and the Australian Radiation Protection and Nuclear Safety Agency (ARPANSA).

HRECs which is assessing research proposals involving exposure of participants to ionising radiation, specifically for research purposes, must be provided with a written report from an accredited medical physicist. Individuals using ionising radiation must hold a valid "license to use", which can be obtained from the Queensland Health Radiation Safety Unit via the institution's Radiation Safety Officer.

### **1.3 Use of Approved and Unapproved Medicines and Medical Devices**

Research within Metro South Health that involves the use of approved or unapproved medicines, medical devices, blood, tissues and chemicals must be compliant with the legislation, regulations and guidelines of the Therapeutic Goods Administration (TGA).

### **1.4 Access to Coronial Material for Research Purposes**

Under Section 53 of the *Coroners Act 2003 (Qld)*, research involving access to coronial material must be referred to the Queensland Health Forensic and Scientific Services Human Research Ethics Committee (FSS-HREC) for ethical and legal approvals by the State Coroner.

### **1.5 Research Involving Adults with Impaired Capacity to Consent**

Under Section 72 of the *Guardianship and Administration Act 2000 (Qld)*, where a person is over the legal age of consent but is unable to give consent, written application to the Queensland Civil and Administrative Tribunal (QCAT) must be undertaken post HREC approval by the researcher.

### **1.6 Research Involving Persons in Custody and/or Staff of Department of Justice and Attorney-General**

All research projects involving persons in custody in Queensland and/or staff of Department of Justice and Attorney-General requires review by the Queensland Department of Justice HREC.

Research projects **only** involving persons in custody and/or staff of Department of Justice and Attorney-General will be reviewed by the Queensland Department of Justice HREC alone. Research projects that also involve other participants should be reviewed by the Queensland Department of Justice HREC and other appropriate institutional HRECs.

### **1.7 Research that May Affect the Health and Wellbeing of Aboriginal People and Communities**

Approval from the Aboriginal Health and Medical Research Council (AH&MRC) Ethics Committee is required where the research project involves research in, or concerning, Metro South Health and any one of the following applies:

- the experience of Aboriginal people is an explicit focus of all or part of the research;
- data collection is explicitly directed at Aboriginal people;
- Aboriginal peoples, as a group, are to be examined in the results;
- the information has an impact on one or more Aboriginal communities; and/or
- Aboriginal health funds are a source of funding.

One of AH&MRC Ethics Committee's major criteria in assessing an application is to ensure that there is Aboriginal community involvement in, and control over, the research. Principal Investigators will need to show evidence that they have the support of each local Aboriginal Community Controlled Health Service (ACCHS) or an alternative appropriate Aboriginal organisation, subject to the agreement of the HREC, where the research is being conducted.



The AH&MRC Ethics Committee reviews applications from the perspective of the impact on Aboriginal people. The review is required in addition to review by a lead or local HREC.

The AH&MRC Ethics Committee accepts applications at any stage in their progress through another HREC. Each Principal Investigator can decide whether they will seek AH&MRC Ethics Committee approval before submitting to other HRECs, or after approval by other HRECs, or simultaneously.

### **1.8 Research Requiring Access to State-wide Data Collections**

All research projects requiring access (including linkage) to state-wide data collections owned or managed by Queensland Health or Queensland Central Cancer Registry must be reviewed by the Queensland Population and Health Services Research HREC. Prior to making a submission to the Queensland Population and Health Services Research HREC, researchers are required to complete a 'Data Custodian Sign-off Form' and submit this with their research proposal to the relevant Data Custodian for review and sign-off.

Researchers wishing to access data from the Queensland Central Cancer Registry are required to complete the 'Data Request Form' and submit it to the Queensland Central Cancer Registry Data Custodian together with the above documentation.

If the research project involves data linkage by the Centre for Health Record Linkage, researchers are required to obtain a letter of support (for technical feasibility) from the Centre for Health Record Linkage prior to HREC review.

### **1.9 Clinical Trials with Persons Unable to Provide Consent**

Under the *Guardianship and Administration Act 2000 (Qld)*, a person unable to consent may not participate in a clinical trial unless the trial has been approved by the Guardianship Tribunal. In reviewing such a trial, the Guardianship Tribunal will decide whether consent can be granted by the person responsible or should be granted by the Tribunal.

The Guardianship Tribunal will not deal with an application for approval of a clinical trial until:

- it receives proof that the relevant ethics committees have approved the clinical trial; and
- all the centres conducting the clinical trial have provided the Tribunal with the patient information sheets and consent forms for the clinical trial.

## **2.0 Animal Research Guidelines**

Animal research falling under one or more of the following categories must comply with relevant NHMRC guidelines:

- research conducted at sites under the control of Metro South Health;
- research involving human participants, their tissue or data, and animals accessed through Metro South Health;
- research conducted by Metro South Health employees;

- research conducted by those acting as agents of Metro South Health; and
- research conducted by organisations in receipt of funding from Metro South Health.

Compliance with relevant NHMRC guidelines is a condition of NHMRC funding to its recipients under the *National Health and Medical Research Council Act 1992 (Cth)*. Furthermore, compliance with NHMRC's Australian Code of Practice for the Care and Use of Animals for Scientific Purposes (2004) is a requirement.

Failure to comply with relevant NHMRC guidelines may result in disciplinary action and withdrawal of NHMRC funding. For an organisation in receipt of NHMRC funding non-compliance may, regardless of the source of funding for a particular research project, place at jeopardy all funding it receives from the NHMRC.

Relevant NHMRC guidelines include, but are not limited to, the following (or their replacement) and any new guidelines that are relevant to the conduct of human and animal research:

- National Statement on Ethical Conduct in Human Research (2007);
- Australian Code for the Responsible Conduct for Research (2007); and
- Australian Code of Practice for the Care and Use of Animals for Scientific Purposes (2004).

Other guidelines issued by the NHMRC, which may be relevant to particular types of research conducted within or supported by Metro South Health are listed below.

- A guide to the use of Australian native mammals in biomedical research – Section 4: Care of individual species (1995) - under review
- Australian Code for the Responsible Conduct for Research (2007)
- Australian Code of practice for the care and use of animals for scientific purposes, 7<sup>th</sup> Edition (2004)
- Ethical guidelines on the use of assisted reproductive technology in clinical practice and research (2007)
- Guidelines for Genetic Registers and Associated Genetic Material (1999)
- Guidelines for the generation, breeding, care and use of genetically modified and cloned animals for scientific purposes (2007)
- Guidelines on Monoclonal Antibody Production (2008)
- Guidelines to promote the wellbeing of animals used for scientific purposes: The assessment and alleviation of pain and distress in research animals (2008)
- Guidelines under section 95 of the Privacy Act 1988 (Cth) (2000)
- Guidelines under section 95A of the Privacy Act 1988 (Cth) (2001)
- National Statement on Ethical Conduct in Human Research (2007)
- NHMRC Guidelines on the Care of Cats Used for Scientific Purposes (2009)

- NHMRC Guidelines on the Care of Dogs Used for Scientific Purposes (2009)
- NHMRC Guidelines on the Use of Animals for Training Interventional Medical Practitioners and Demonstrating Medical Equipment and Techniques (2009)
- Policy on the care and use of non-human primates for scientific purposes (2003) - under review
- Values and Ethics: Guidelines for ethical conduct in Aboriginal and Torres Strait Islander health research (2003)