

1. Statement

The Department of Health (the Department) shall ensure that all human research is conducted in a safe and ethical manner with open and transparent use of resources by utilising a sound research governance framework within the Department.

2. Purpose

The purpose of this policy is to ensure that all research conducted by the Department or in collaboration with Hospital and Health Services and/or external entities is of the highest ethical and scientific standard and compliant with relevant legislation, codes of conduct, national best practice guidelines and Standard Operating Procedures.

3. Scope

This policy applies to all Department employees, volunteers, contractors, consultants and external entities who propose to undertake, administrate, review and/or govern human research involving the Department.

4. Principles

4.1 General Principles for the conduct of research within the Department:

The Department requires

- minimisation of duplication of ethical review and legal review for multi-centre research
- transparent and accountable research governance processes
- research to be adequately resourced
- prompt, sensitive and fair management of any reported incidents of research misconduct
- all research to be undertaken in accordance with legislative and other requirements as outlined in *Section 5: Legislative or other authority*, and *Section 6. Supporting Documents*
- research governance processes to be undertaken in parallel with ethical review
- research to be authorised by the relevant delegate prior to commencement.

4.2 Ethical Review of Research

4.2(a) All human research directly involving Departmental staff, patients or resources shall be reviewed and approved by a public health service based Human Research Ethics Committee (HREC) that:

- is registered and operates in accordance with the National Health and Medical Research Council (NHMRC) and its guiding documents as outlined in Section 5, and
- has a Memorandum of Understanding or other agreement in place with the Department to recognise mutual acceptance of ethical review, and

- utilises a research ethics database that has interoperability with the research ethics database used by the Department

4.2(b) All research using only data resources of the Department shall be:

- reviewed by an HREC that is registered with the NHRMC and
- conducted according to National and State legislation

4.3 Research Governance

No research shall commence until:

- a research governance process has been undertaken
- the research has been authorised by the appropriate delegate.

5. Legislative or other authority

- *Ambulance Services Act 1991*
- *Australian Institute of Health and Welfare Act 1987 (Cth)*
- *Copyright Act 1968 (Cth)*
- Copyright Regulations 1969
- *Coroners Act 2003*
- *Financial Management and Accountability Act 1997 (Cth)*
- *Financial Accountability Act 2009*
- Financial and Performance Management Standard 2009
- *Gene Technology Act 2000 (Cth)*
- Gene Technology Regulations 2001 (Cth)
- *Guardianship and Administration Act 2000*
- *Health Services Act 1991 (Cth)*
- *Hospital and Health Boards Act 2011*
- *Information and Privacy Act 2009*
- *Privacy Act 1988 (Cth)*
- *Prohibition of Human Cloning Act 2002 (Cth)*
- *Prohibition of Human Cloning for Reproduction and the Regulation of Human Embryo Research Amendment Act 2006*
- *Public Health Act 2005*
- *Public Service Act 2008*
- *Research Involving Human Embryos Act 2002 (Cth)*
- *Therapeutic Goods Act 1989 (Cth)*

- Therapeutic Goods Regulations 1990 (Cth)
- Therapeutic Goods (Medical Devices) Regulations 2002 (Cth)
- *Transplantation and Anatomy Act 1979*
- Australian Research Council Funding Rules
- Australian Radiation Protection and Nuclear Safety Agency (ARPANSA) 2005, Code of Practice for the Exposure of Humans to Ionizing Radiation for Research Purposes
- Australian Radiation Protection and Nuclear Safety Agency (ARPANSA) 1995, Recommendations for Limiting Exposure to Ionizing Radiation and National Standard for Limiting Occupational Exposure to Ionizing Radiation (reprinted 2002)
- Commonwealth Grant Rule and Guidelines 2014
- Guidelines for Good Pharmaco-Epidemiology Practices (GPP) 2007
- National Health and Medical Research Council (NHMRC) 2015, NHMRC Administering Institutions Policy
- National Health and Medical Research Council (NHMRC) 2012, Framework for Monitoring: Guidance for the National Approach to Single Ethical Review for Multi-centre Research
- National Health and Medical Research Council (NHMRC) 2008, Guidelines to Promote the Wellbeing of Animals Used for Scientific Purposes
- National Health and Medical Research Council (NHMRC) 2012, National Certification Handbook
- National Health and Medical Research Council (NHMRC) 2007, National Statement on Ethical Conduct in Human Research (updated March 2014)
- National Health and Medical Research Council (NHMRC) 2011, Research Governance Handbook: Guidance for the National Approach to Single Ethical Review
- National Health and Medical Research Council (NHMRC) and Universities Australia 2007, Australian Code for the Responsible Conduct of Research
- National Health and Medical Research Council (NHMRC) Funding Rules
- Queensland State Archives Health Sector (Clinical Records) Retention and Disposal Schedule (QDAN 683 v.1)
- Therapeutic Goods Administration 2004, Access to Unapproved Therapeutic Goods – Clinical Trials in Australia
- Therapeutic Goods Administration 2000, Note for Guidance on Clinical Safety Data Management: Definitions and Standards for Expedited Reporting
- Therapeutic Goods Administration 2000, Note for Guidance on Good Clinical Practice (CPMP/ICH/135/95) Annotated with TGA comments
- Therapeutic Goods Administration 2006, The Australian Clinical Trial Handbook

6. Supporting documents

- Guideline: External Research Funding and Infrastructure Support
- Policy: Credentialing and Defining the Scope of Clinical Practice (QH-POL-390:2014)
- Queensland Government 2011, Code of Conduct for the Queensland Public Service
- Queensland Government Indemnity Guideline
- Standard: Research Management

Version Control

Version	Date	Comments
1	2010	New document
1.2	06/2012	Review and editorial update
2	23/06/2015	Policy Rationalisation Project