Queensland Health

Research management

Department of Health Policy

QH-POL-013:2022

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:

- 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. Legislation and related documents

- *Animal Care and Protection Act 2001*
- Australian Code for the Responsible Conduct of Research, (2007) (Updated 2018)
- Australian code for the care and use of animals for scientific purposes 8th edition 2013 (updated 2021)
- AIATSIS Code of Ethics for Aboriginal and Torres Strait Islander Research (2020)
- Code for Radiation Protection in Planned Exposure Situations (2020)
- Code of Practice Exposure of Humans to Ionizing Radiation for Research Purposes 2005 (Cth)
- *Coroners Act 2003 (Qld)*
- *Defence Trade Controls Act 2012 (Cth)*

- Ethical Conduct in research with Aboriginal and Torres Strait Islander Peoples and communities: Guidelines for researchers and stakeholders (2018)
- Fundamentals for Protection Against Ionising Radiation (2014)
- Framework for Monitoring: Guidance for the national approach to single ethics review for multi-centre research, 2012.
- *Gene Technology Act 2000 (Cth)*
- *Gene Technology Regulations 2001 (Cth)*
- *Guardianship and Administration Act 2000 (Qld)*
- Guide to Managing and Investigating Potential Breaches of the Australian Code for the Responsible Conduct of Research (2018)
- Guide for Radiation Protection in Existing Exposure Situations (2017)
- Guidelines to Promote the Wellbeing of Animals Used for Scientific Purposes, 2008
- Guidelines for Good Pharmacoepidemiology Practices, 2015
- Health Sector (Clinical Records) Retention and Disposal Schedule
- Health Sector (Corporate Records) Retention and Disposal Schedule
- *Hospital and Health Boards Act 2011 (Qld)*
- *Information Privacy Act 2009 (Qld)*
- Keeping research on track II
- National Standard Operating Procedures for Clinical Trials
- National Principles for Teletrials in Australia
- National Certification Handbook, 2012
- National Statement on Ethical Conduct in Human Research, (2007) (Updated 2018), as amended from time to time
- Note for Guidance on Clinical Safety Data Management: Definitions and Standards for Expedited Reporting, 2000
- *Powers of Attorney Act 1998 (Qld)*
- *Privacy Act 1988 (Cth)*
- *Prohibition of Human Cloning for Reproduction Act 2002 (Cth)*
- *Public Health Act 2005 (Qld)*
- Queensland Public Sector Health System Multi-Site Research Collaboration Agreement Standard Terms
- Regulatory Impact Statement Code of Practice Exposure of Humans to Ionizing Radiation for Research Purposes

- Research Governance Handbook: Guidance for the national approach to single ethical review, 2011
- Research involving patients who are unable to give consent Policy Statement (April 2018)
- *Research Involving Human Embryos Act 2002 (Cth)*
- *Research Involving Human Embryos and Prohibition of Human Cloning for Reproduction Act 2003 (Qld)*
- Research Involving Human Embryos and Prohibition of Human Cloning for Reproduction Regulation 2015 (Qld)
- *Therapeutic Goods Act 1989 (Cth)*
- Therapeutic Goods Administration ICH Guideline for Good Clinical Practice
- *Therapeutic Goods Regulations 1990 (Cth)*
- *Transplantation and Anatomy Act 1979 (Qld)*
- Values and Ethics - Guidelines for Ethical Conduct in Aboriginal and Torres Strait Islander Health Research

5.1 Supporting documents

- Australasian Tele-Trial Model Access to Clinical trials closer to home using tele-health
- Guideline for researchers- disclosure of confidential information
- Medicines Australia Clinical Trial Research Agreements
- Medicines Australia Forms of Indemnity
- Medical Technology Association of Australia Clinical Investigation Research Agreement
- Medical Technology Association of Australia Form of Indemnity
- Medical Technology Association of Australia Compensation Guidelines
- NHMRC Standardised Participant Information and Consent Forms
- Research using material from coronial autopsies
- Standard Operating Procedures for Queensland Health HREC Administrators
- Standard Operating Procedures for Queensland Health RGOs
- Therapeutic Good Administration
    - Access to Unapproved Therapeutic Goods
    - Clinical Trials
    - Clinical Trial Handbook

6. Definitions

Term	Definition
calendar day	means a day of the calendar year, including weekends and public holidays.
certified HREC	means a HREC which has had its processes assessed and certified under the NHMRC National Certification Scheme. For more information about requirements for HRECs regarding multi-centre research: National Certification Scheme for the ethics review of multi-centre research.
clinical research	has the meaning defined in section 13(1) of schedule 2 of the Guardianship and Administration Act 2000 (Qld).
clock day	means each calendar day after a valid application has been received and is being processed excluding time taken for the applicant to respond to queries with further information that enables processing to recommence. That is, clock days are not a measure of total time elapsed since a valid application is received but, instead, are a measure of processing time.
confidential information	means information designated as 'confidential information' under health portfolio legislation.
coronial investigation document	coronial investigation document has the same meaning as 'investigation document' as defined in the Coroners Act 2003 (Qld).
Department of Health	means the department of the Queensland Government named 'Queensland Health' or its successor.
Ethics Review Manager	means a secure web-based Research Ethics Database where researchers upload research application forms and HREC administrators and RGOs review those applications and report outcomes of HREC and research governance reviews.
HHB Act	means the Hospital and Health Boards Act 2011 (Qld).
HHS	means a Hospital and Health Service established under section 17 of the HHB Act.
Human Research Ethics Committee (HREC)	means a committee registered by the NHMRC and constituted under the guidance of the NHMRC National Statement on the Ethical Conduct in Human Research (2007) (Updated 2018), as amended from time to time, to conduct the ethical and scientific review of a human research project whose members have been appointed by a HSCE.
HSCE	means a Health Service Chief Executive or delegate.
in-kind support	means support in the form of goods, services, resources, or other support but not money.

Term	Definition
low risk	means research in which the only foreseeable risk is no more than discomfort.
multi-centre research	means a research project undertaken by a group of institutions (or individuals) at more than one site.
National Mutual Acceptance Scheme	means the national approach to single ethical review of multi-centre research in which participating states of Australia have agreed to accept the scientific and ethical review of an HREC from a public health facility located outside of the institution's state.
NHMRC	means the National Health and Medical Research Council.
PH Act	means the Public Health Act 2005 (Qld).
Principal Investigator (PI)	means the individual who is responsible for the overall conduct, management, monitoring and reporting of research conducted at a participating site and submits the research project for site authorisation for that site. There will be one Principal Investigator per site.
QCAT	means the Queensland Civil and Administrative Tribunal.
Queensland Health	means the public sector health system which is comprised of the HHSs and the Department of Health pursuant to section 8 of the HHB Act.
Research Application	means the research ethics and governance application form (as approved by Queensland Health from time to time) and all required supporting documentation.
RGO	Research Governance Officer.
satellite site	means a satellite site that is located in a geographically separate health facility from the primary site and responsibility is delegated by the primary site (clinical trial site) to perform activities associated with the conduct of a clinical trial and to support trial accessibility of remote participants to a clinical trial.
teletrial	means a clinical trial conducted from a primary clinical study site utilising telehealth communication to engage access to satellite sites, forming a clinical trials cluster in designated regions to enhance patient reach, recruitment, and management.
valid	means an application that is in a state so it can be referred for a decision. A valid governance application is one which is deemed complete by the RGO (that is, it contains all relevant signatures and supporting documentation uploaded into ERM), and all RGO queries have been addressed

Version control

Version	Date	Comments
1	2010	*New document*
1.1	June 2012	*Review and editorial update*
2	23 June 2015	*Policy Rationalisation Project*
3	11 August 2022	*Align with Queensland Health Research Ethics and Governance Standard Operating Procedures*