Queensland Health

Research management

Department of Health Standard

QH-IMP-013-1:2022

1. Statement

This Standard identifies the minimum and auditable requirements that evidence the implementation of the Research Management Policy for meeting responsibilities associated with the conduct of research involving the Department of Health, including the ethical and scientific review of research, contractual and financial management of research and research authorisation by the relevant authority.

2. Scope

This standard applies to all Department of Health employees and external parties (including contractors, consultants, students and volunteers) who propose to undertake, administrate, review and/or govern human research involving any resources – human, financial and/or material – of the Department.

3. Requirements

3.1. Research Governance Including Ethical and Scientific Review of Human Research

3.1.1. General requirements for all research projects

- All human research being undertaken in the Department of Health must undergo ethical review by a Human Research Ethics Committee (HREC) registered with the National Health and Medical Research Council (NHMRC), and also complete research governance processes.
- Health research is categorised according to the level of risk of the project:
  - Low or Negligible Risk (LNR) research or
  - research where the level of risk is greater than LNR.

If in doubt, researchers should contact their local Human Research Ethics Committee (HREC) to discuss the proposed research and confirm the level of risk of the project.

- All research applications must be made using one of the two forms: Human Research Ethics Application (HREA) or the Ethics Review Manager (ERM) version of the HREA located on the ERM website.
- All research must comply with National and State legislation and guidance as outlined in Section 4: Legislation and related documents.

- The HREC will review the Research Application and make a decision:
  - for an application not requiring review by a full HREC, within 60 clock days from the date of HREC administrator referral for a decision; or
  - for an application requiring review by a full HREC, within 60 clock days from the meeting closing date for submission (notice of which is publicly available) of valid applications eligible for review by the next meeting of the relevant full HREC.
- A Site Specific Assessment (SSA) form must be completed for research governance and to enable departmental authorisation, prior to the Department resources being utilised for research.
- The Director-General (or their delegate) will review the application and make a decision whether to authorise the carrying out of the research activity proposed in the research application within 25 clock days from the date of acknowledgement by the RGO of a valid SSA (i.e., referral for a decision).
- A fee may be levied for ethical review and governance processing of commercially sponsored research.
- The Department of Health acknowledges the importance of and is committed to promoting the progression and retention of women in health and medical research.

3.1.2. Low or negligible risk (LNR) research

- For LNR research involving only the risk of inconvenience, an HREC may choose to grant exemption from full HREC review and offer an alternative review process.
- If the researcher is requesting a waiver of consent, the project must be reviewed by a full HREC. A Public Health Act 2005 (PHA) approval may also be required.

3.1.3. Research higher than low or negligible risk

- All human research (including research involving gene therapy and related gene technologies including xenotransplantation) defined by the NHMRC as being higher than LNR, conducted in or in collaboration with the Department and utilising Departmental facilities, data or staff, shall at a minimum, be reviewed by a public health service HREC that is registered with the NHMRC.

3.2. Ethical and Scientific Review of Animal Research

3.2.1. Ethical and Scientific Review of Animal Research

- Department of Health facilities involved in animal research as defined by the NHMRC Guidelines to Promote the Wellbeing of Animals Used for Scientific Purposes 2008 are required to ensure that research on animals conforms to the Commonwealth, National and State guidelines, policies and legislation relating to the ethical conduct of animal research.

- Animal research must be reviewed by an Animal Ethics Committee (AEC) that practices in accordance with the Australian code for the care and use of animals for scientific purposes 8th edition 2013 (updated 2021). Facilities lacking Animal Ethics Committees (AEC), but undertaking animal research, should have an agreement with an external organisation to have access to a registered AEC or use the Queensland Health Forensic and Scientific Services Animal Ethics Committee. All research should comply with the regulatory requirements for animal research as set by the Forensic and Scientific AEC or collaborating organisations (e.g., Universities / Research institutions).

3.3. Research using Gene Technologies and Related Therapies

3.3.1. Research using Gene Technologies and Related Therapies

- Researchers from the Department are required by law to abide by national and state legislation for the regulation of Genetically Modified Organisms (GMOs) in Australia as defined in the Gene Technology Act 2000 and the Gene Technology Regulations 2001.
- Departmental facilities in which researchers are using gene technology or undertaking dealings (as defined in the legislation) should be accredited and maintain, or have an established link with, a properly constituted Institutional Biosafety Committee (IBC) within a collaborating organisation.

3.4. Ionising Radiation

3.4.1. Ionising Radiation

- All research involving any form of radiation should comply with 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).
- Ethics committees assessing research proposals involving exposure of participants to ionising radiation should be provided with a written report from an accredited medical physicist.
- Individuals using ionising radiation should hold a valid 'License to Use', which can be obtained from Radiation Health, Health Protection Unit, Queensland Health, via the Institution's Radiation Safety Officer.

3.5. Use of Approved and Unapproved Medicines and Medical Devices

3.5.1. Use of Approved and Unapproved Medicines and Medical Devices

- Research that involves the use of approved or unapproved medicines, medical devices, blood, tissues and chemicals should be compliant with the legislation, regulations and guidelines of the Therapeutic Goods Administration.
- Please refer to the Medicines and Poisons (Medicines) Regulation 2021.

3.6. Access to Coronial Material for Research

3.6.1. Access to Coronial Material for Research

- Under section 53 of the Coroners Act 2003 research involving access to coronial material should be referred to the Queensland Health Forensic and Scientific Services Human Ethics Committee for ethical review as well as legal approvals by the State Coroner.

3.7. Research involving adults with impaired capacity to consent

3.7.1. Research involving adults impaired capacity to consent

- Under section 72 of the Guardianship and Administration Act 2000, where a person is over the legal age of consent but is unable to give consent for participation in a clinical trial, a written application to the Queensland Civil and Administrative Tribunal (QCAT) by the researcher should be undertaken after HREC approval has been granted.

3.8. Risk Management

3.8.1. Risk Management

- Risk assessment informs the monitoring of research that is dependent on the level of risk and is undertaken by the HREC and RGO. It may include:
    - annual reports for all approved research, due on the anniversary of the HREC approval
    - resource utilisation
    - contract management
    - Data Safety and Monitoring Board (DSMB) reports (or other nominated safety committee)
    - a Risk Assessment Report may be required for investigator initiated research
    - reporting of serious adverse events (SAE) or serious unexpected suspect adverse reactions (SUSARs) in accordance with the NHMRC Safety Monitoring and Reporting in Clinical Trials Involving Therapeutic Goods.

3.9. Consent

3.9.1 General principles for consent

- consent to participate in a research project shall comply with the principles and guidelines for consent as described in the NHMRC's National Statement on Ethical Conduct in Human Research 2007 (Updated 2018), (the National Statement)
- when seeking consent, researchers shall:
    - never use coercion or pressure with potential participants

    - re-negotiate the consent where projects have an extended duration (if requested by the Reviewing HREC) or significant amendments
- people who elect to not participate need not give any reason for their decision, and should suffer no repercussions as a result of their decision
- research participants are entitled to withdraw from a research project at any time and should be informed about the consequences of any withdrawal.

3.9.2. Opt out consent

- Can only be used for LNR research that is approved by a full HREC
- PHA approval may also need to be obtained if the research requires the use of potentially re-identifiable or identifiable confidential health information
- does not constitute Consent when applying Commonwealth and State legislation
- requires the provision of information to potential participants, including full disclosure of the research project, the management of participants' confidential information and the methods by which they can decline to participate
- can only be used if participants receive and read the information provided, and understand they are able to act on this information to decline to participate.

3.9.3. Waiver of consent

- can only be used for LNR research if it has been approved by a full HREC
- PHA approval may also need to be obtained if the research requires the use of potentially re-identifiable or identifiable confidential health information. Chapter 6, Part 4, Division 2, s281-284 of the Public Health Act 2005 shall be considered.

3.9.4 Consent for future unspecified use of data or tissue

- Research that seeks approval to use personal information (data or tissue) in a project, and to also use the personal information in future unspecified research must obtain HREC approval for the current and future unspecified use. This may include permission to store personal information in data or tissue banks
- the consent for the initial collection of personal information must also clearly state to potential participants, the terms and wide-ranging implications of them agreeing to the future unspecified use of their personal information in research. This consent must be clearly documented
- future research projects relying on previously approved consent for future unspecified use must describe in the HREC application, the terms and use of that unspecified consent

3.10. Conflicts of Interest

3.10.1 General principles

- Conflicts of interest may exist where a person's or institution's interests or responsibilities have the potential to influence the carrying out of institutional roles or research obligations.
- Conflicts may relate to financial interests, other private, professional or institutional benefits or advantages that depend on the research outcomes.
- The values of clinical care, welfare of society and science should prevail over commercial imperatives and monetary values.
- Conflicts of interest must be appropriately managed so as to not compromise the validity and integrity of the research process and undermine public confidence in the institution.

3.10.2 Dealing with conflicts of interest

- Transparent processes to identify and manage actual, perceived and potential conflicts of interest that involve HRECs, research reviewers, funding review committees, researchers or research participants must be in place.

3.11 Research Governance

3.11.1 General requirements for all research projects

- Research governance should be undertaken in parallel with the HREC review using the Site Specific Assessment form which is in the ERM website
- Research governance covers areas such as finance, intellectual property, contracts and site resource utilisation.
- Research may not commence until ethical review and governance procedures are completed and the project has received authorisation from the Chief Executive or delegate.

3.11.2 Financial management

- Management of all research project funds and revenue within the Department of Health shall be compliant with this policy and Queensland public sector policy and legislation.
- Budgets for all research are to be developed and approved by the relevant Business or Finance Manager.
- In-kind support is to be costed as far as possible and included in the budget spreadsheet.
- Project budgets should be adjusted according to the Consumer Price Index (CPI) on the anniversary of the contract execution date.

- Research that is funded, regardless of the source of funding, should have an individual cost centre number or other means of identification for auditing purposes.

3.11.3 Contract management

- Depending on the level of risk and liability, research involving the Department may require a written contract.
- The authority for signing of contracts on behalf of the Department is the Director-General or delegate, as designated by Corporate Delegations Framework.
- All contracts may be subject to legal review.

3.11.4 Publication of research

- Researchers have a duty to ensure that research results are disseminated and communicated, whether favourable or unfavourable, in ways that permit scrutiny and contribute to public knowledge and understanding.
- Before proceeding to publication of any research findings, Intellectual Property matters must be addressed. Research contracts or agreements must appropriately protect intellectual property rights of the institution, the researcher, research trainees and sponsors of the research.
- The host institution and funding sources of the research should be acknowledged in any publications, along with a statement that the research has not been subject to result-dependent funding or veto of publication by a sponsor and / or government.
- Government sponsors reserve the right to review manuscripts for a defined period of time before publication, to allow strategies and / or policies to be developed in response to the research findings. These time limits should be cited in the research contract / agreement.
- Manuscripts should include a statement that the project has undergone ethical review prior to commencement of the project (or was exempt from full ethical review).
- Research projects cannot be approved retrospectively by an HREC.

4. 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

4.1 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

5. 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.

Term	Definition
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.
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	June 2010	*New document*
1.1	December 2010	*Editorial update*
2	23 June 2015	*Policy Rationalisation Project*
3	11 August 2022	*Align with Queensland Health Research Ethics and Governance Standard Operating Procedures*