Research Management Standard

QH-IMP-013-1:2015

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 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 (LNR form or the National Ethics Application Form (NEAF)) from the *Online Forms* website https://au.ethicsform.org/SignIn.aspx
- Multi centre research, regardless of the level of risk, must be submitted to the Central Coordinating Service (CCS) for allocation to an HREC certified by the NHMRC to review multi-centre research (for further information, see website http://www.health.qld.gov.au/ohmr/html/regu/cen_coord_serv.asp).
- All research must comply with National and State legislation and guidance as outlined in Section 5: Legislative or other authority, and Section 6. Supporting Documents.
- A benchmark of 60 calendar days has been set for the completion of the ethical and scientific review process. The review time does not include the time taken for the researcher to respond to HREC requests for additional or amended information.

- A Site Specific Assessment (SSA) form must be completed for research governance and to enable Departmental Authorisation, prior to Department resources being utilised for research.
- A benchmark of 25 calendar days has been set for the completion of research governance processes including contract management. The review time does not include the time taken for the researcher to respond to requests from the Research Governance Officer (RGO) for additional or amended information.
- 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 will also be required. See website http://www.health.qld.gov.au/ohmr/html/regu/aces_conf_hth_info.asp for more information.

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 http://www.nhmrc.gov.au/health-ethics/human-research-ethics-committees-hrecs/list-human-research-ethics-committees-registere

3.2 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 ed., 2013).
- 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 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

- 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.
- Research must be assessed and comply with recommendations made by the NHMRC's Human Genetics Advisory Committee (HGAC) https://www.nhmrc.gov.au/about/nhmrc-committees/human-genetics-advisory-committee-hgac and the IBC prior to review and approval from an HREC.

3.4 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

- 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.

3.6 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 and legal approvals by the State Coroner.

3.7 Research involving adults with 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

- Risk assessment and monitoring of research 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, based on the Queensland Health Risk Management Framework and Risk Management Policy (Policy # QH-POL-070:2014) may be required for investigator initiated research
- reporting of serious adverse events (SAE) or serious unexpected suspect adverse reactions (SUSARs).

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* (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 must also 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 privacy 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 must also 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 SSA form which is created from either the LNR or NEAF forms from the *Online Forms* 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 the Legal and Governance Delegations Guide.
- 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. Responsibility and Accountability

Position	Responsibilities	Accountabilities / Audit Criteria
Senior Director Preventive Health Unit	This position is accountable and responsible for: • Providing advice to the Director-General and Minister for Health on research support and funding matters	

Position	Responsibilities	Accountabilities / Audit Criteria
Director Health & Medical Research Preventive Health Unit	This position is accountable and responsible for: • Overseeing the development and revision of the Research Management Policy and Standards	

5. Related legislation and documents

5.1 Legislation

- *Ambulance Services Act 1991*
- *Animal Care and Protection Act 2001*.
- *Australian Institute of Health and Welfare Act 1987* (Cth)
- *Copyright Act 1968* (Cth)
- *Coroners Act 2003*
- *Financial Framework (Supplementary Powers) Act 1997* (Cth)
- *Financial Accountability Act 2009*
- *Gene Technology Act 2000* (Cth)
- *Gene Technology Act 2001*
- *Guardianship and Administration Act 2000*
- *Hospital and Health Boards Act 2011*
- *Information and Privacy Act 2009*
- *Privacy Act 1988* (Cth)
- *Prohibition of Human Cloning for Reproduction Act 2002* (Cth)
- *Prohibition of Human Cloning for Reproduction and the Regulation of Human Embryo Research Amendment Act 2006* (Cth)
- *Public Health Act 2005*
- *Public Service Act 2008*
- *Research Involving Human Embryos Act 2002* (Cth)
- *Therapeutic Goods Act 1989* (Cth)
- *Transplantation and Anatomy Act 1979*

5.2 Supporting documents

- 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)
- Australian Research Council Funding Rules
- Commonwealth Grant Rule and Guidelines 2014
- Financial and Performance Management Standard 2009
- Guideline: External Research Funding and Infrastructure Support
- Guidelines for the generation, breeding, care and use of genetically modified and cloned animals for scientific purposes
- 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) Funding Rules
- 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
- Policy: Credentialing and Defining the Scope of Clinical Practice (QH-POL-390:2014)
- Queensland State Archives Health Sector (Clinical Records) Retention and Disposal Schedule (QDAN 683 v.1)
- Queensland Public Sector. Intellectual Property Principles, Version 2: 2013
- Therapeutic Goods Administration 2004, Access to Unapproved Therapeutic Goods – Clinical Trials in Australia
- Queensland Government 2011, Code of Conduct for the Queensland Public Service
- Queensland Government Indemnity Guideline
- Standard: Research Management
- 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
- Therapeutic Goods Regulations 1990 (Cth)
- Therapeutic Goods (Medical Devices) Regulations 2002 (Cth)

6. Definitions

Term	Definition
Central Coordinating Service (CCS)	A service provided by the Department of Health for the allocation of all multi-centre studies that involve more than one HREC, including clinical trials and collaborative trials undertaken within or in association with Queensland Health.
Human Research Ethics Committee. (HREC)	Human Research Ethics Committees (HRECs) review research proposals that involve humans or their tissue or data research involves humans. HRECs are established by organisations, which register their HREC with the NHMRC. It may also be referred to as the Reviewing HREC in multi-centre research studies.
Low or Negligible Risk Form (LNR Form)	An application form used for research which is defined as low or negligible risk. The form is available on the Online Forms website. https://www.ethicsform.org/au/SignIn.aspx
Multi-centre Research	Includes research conducted through the collaboration of at least two unique institutions that may be situated in more than one state or territory or within a single jurisdiction. It does not refer to research being conducted at several sites or locations of a single institution. (Certification Handbook – National Certification Scheme of Institutional Processes related to the Ethical Review of Multi-centre Research, November 2012, p 1) Multi-centre research must be allocated via the CCS for HREC review.
The National Statement	The National Statement on Ethical Conduct in Human Research (2007) Revised 2009. A guidance document developed by the NHMRC, the Australian Research Council and the Australian Vice-Chancellors' Committee to provide guidelines for researchers, HRECs and others conducting ethical review of research. It also states institutions' responsibilities for the quality, safety and ethical acceptability of research that they sponsor or permit to be carried out under their auspices. http://www.nhmrc.gov.au/guidelines/publications/e72
National Ethics Application Form. (NEAF)	There are two formats for this document – the NHMRC version, and the Online Forms version. Both formats are acceptable for HREC review. The Online Forms version is the preferred form for use in Queensland Health HRECs. The NHMRC version of the form must be transferred to the Online Forms version to enable it to be uploaded to research ethics database. The Site Specific Assessment form (SSA) is only able to be created out of the Online Forms version of the NEAF.

Term	Definition
Online Forms	The *Online Forms* website is an online system that enables users to complete their applications for research ethics and governance review electronically. The website hosts a licensed copy of the NHMRC's NEAF, as well as the site specific assessment forms for the public health systems of New South Wales, Queensland, South Australia and Victoria. www.ethicsform.org/au/SignIn.aspx
Serious Adverse Event (SAE)	The definition of a Serious Adverse Event (SAE) will be defined by the Sponsor and included in the Protocol. Generally, an SAE in human drug trials is defined as any untoward medical occurrence that at any dose, results in death, is life-threatening, requires inpatient hospitalization or prolongation of existing hospitalization, results in persistent or significant disability/incapacity, is a congenital anomaly/birth defect, or requires intervention to prevent permanent impairment or damage. Suspected Unexpected Serious Adverse Reactions (SUSARs) are considered a subset of SAEs.
Site Specific Assessment (SSA) Form	A tool to assist Research Governance Officers in the research governance process to document the level of support and suitability of a research study to be conducted at a site, irrespective of whether that study is multi-centre or single site.
Research Governance	The process by which a Research Governance Officer assesses the suitability of study to take place within the Department and recommends authorisation of a project. Once authorised, the study may commence at that site.

Version Control

Version	Date	Comments
1	June 2010	New document
1.1	December 2010	Editorial update
2	23 June 2015	Policy Rationalisation Project