

Health Service Directive

Directive # QH-HSD-035:2016
Effective Date: 15 November 2016
Review Date: 15 November 2019
Supersedes: # QH-HSD-035:2013

Research Ethics and Governance

Purpose

The purpose of this Health Service Directive (HSD) is to ensure consistency across Hospital and Health Services (HHSs) in research ethics and governance processes.

Scope

This HSD applies to all HHSs.

Principles

- The Department of Health provides advice, training and education to enable HHS compliance with this HSD.
- All research involving humans or their data or tissue is conducted in a manner consistent with nationally recognised human research ethics and governance guidelines and legislation.
- All efforts are made to minimise duplication of Human Research Ethics Committee (HREC) review of research, and legal review of research agreements for multicentre research.
- A fair and transparent research management process is used to investigate reported research misconduct and complaints.
- Where appropriate all research has a plan of translation to the local community.
- Conflicts of interest must be disclosed and managed for all research to protect the integrity of the research process prior to ethical consideration and commencement of research.

Outcomes

All HHSs will achieve the following outcome:

- Consistent research ethics and governance processes that facilitate research and allow for valid and accurate research activity reporting.

Mandatory requirements

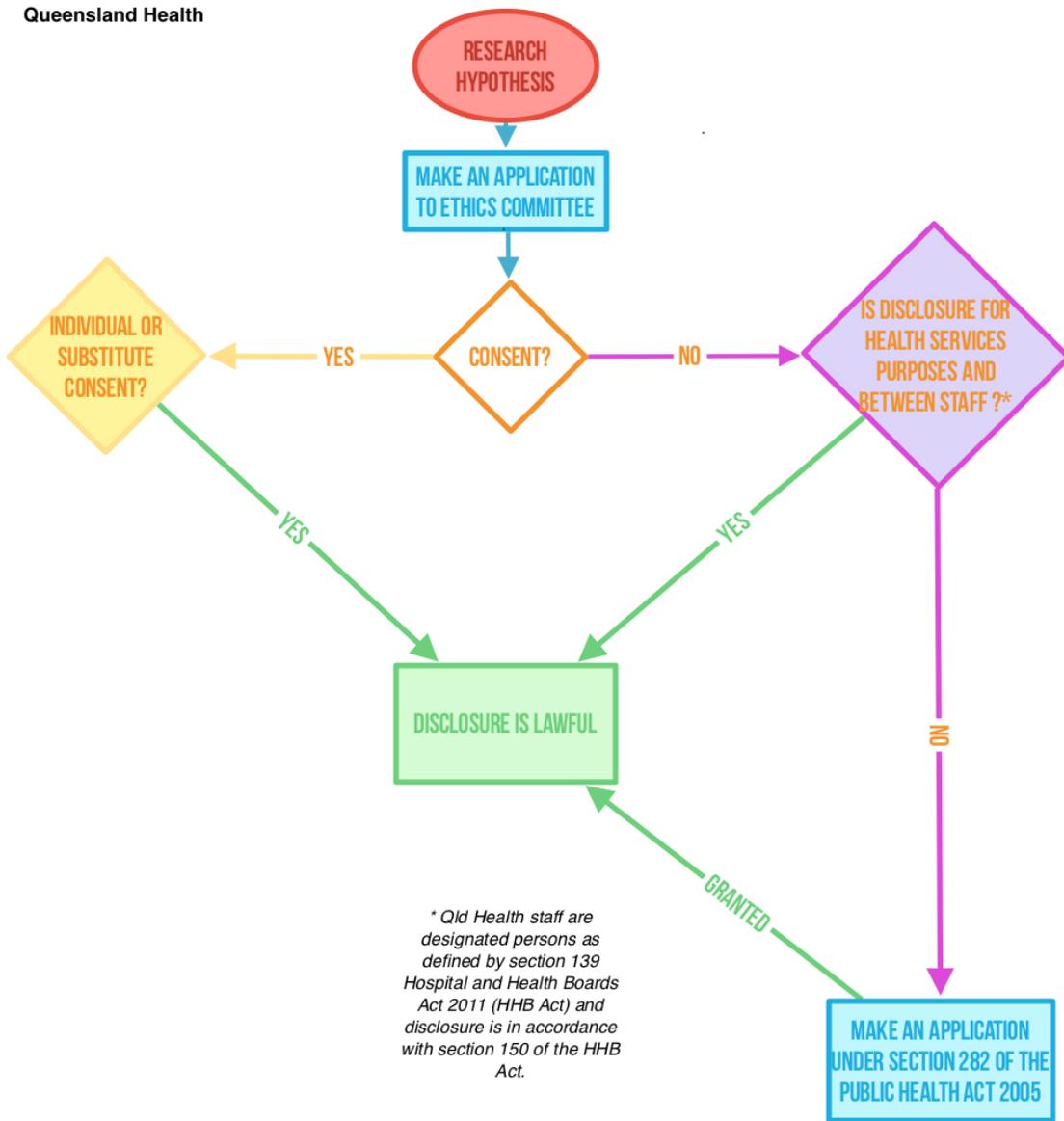
- Researchers will upload all research ethics and governance applications (including supporting documentation) through [Online Forms](#) (or its replacement).
- All research applications will be administered through the Australian Research Database (AU RED) (or its replacement) in accordance with the specifications of the database custodian – Health Innovation, Investment and Research Office (HIIRO).
- All research applications must comply with:
 - the National Health and Medical Research Council (NHMRC) *National Statement on Ethical Conduct in Human Research*, 2007, including monitoring responsibilities; and
 - the NHMRC, Australian Research Council and Universities Australia *Australian Code for the Responsible Conduct of Research*, 2007.
- When requested, Research Governance Officers (RGOs) will accept research governance applications in parallel with HREC applications.
- RGOs will accept Department of Health approved document templates to streamline research governance processes, for example the Medicines Australia template research agreements, as amended from time to time.
- HREC administrators and RGOs will register an application in AU RED within two business days of receipt of the application, except in the case of advertised research office closures.
- The period to determine an ethics decision will not exceed 60 clock days from receipt of a valid application.
- The period to determine a research governance decision (that is authorisation of research or not) will not exceed 25 clock days from receipt of a valid application.
- Eligible multicentre research will be reviewed once only by a certified HREC under the National Mutual Acceptance Scheme or Statewide Ethics Review processes.
- All clinical trials must be conducted in accordance with the requirements of:
 - the [Therapeutic Goods Administration Act 1989](#) (Cth);
 - the adopted Therapeutic Good Administration [Note for Guidance on Good Clinical Practice \(CPMP/ICH/135/95\)](#); and
 - [ISO 14155 Clinical investigation of medical devices for human subjects - Good Clinical Practice](#) (for devices).
- All ethics approved research will undergo a research governance review and will not be authorised without an adequate research budget (actual and in-kind support).



- Researchers are required to outline their plan to translate research into practice. Reference to the research translation plan will be included in the elements contained in the ethics application under the following headings: Research Question/Aims; Research Methodology; Feasibility; and Outcomes.
- All research involving access to coronial investigation documents must be referred to the Department of Health Forensic and Scientific Services Human Ethics Committee.
- Where a person is over the legal age of consent but lacks capacity and is unable to give informed consent to participate in clinical research, the researcher must make a written application to Queensland Civil and Administrative Tribunal (QCAT) to review and approve the clinical research. QCAT requires evidence of prior HREC approval. The QCAT requirements for approval of clinical research are set out in schedule 2, section 13 of the *Guardianship and Administration Act 2000* (Qld).
- Section 72 of the *Guardianship and Administration Act 2000* (Qld) sets out how QCAT may consent, for an adult with impaired capacity for the special health matter concerned, to the adult's participation in special medical research or experimental health care. QCAT requires evidence of prior HREC approval. Accordingly, in these circumstances, the researcher must make a written application to QCAT to review and consent to the participation in special medical research or experimental health care.
- In addition to ethics approval, where the research requires a Queensland Health employee to disclose confidential information about a patient to a researcher, the researcher must identify a lawful authority for the use or disclosure of that information (refer to Diagram 1). Lawful authority may include:
 - disclosure with consent;
 - disclosure between Queensland Health employees or other designated persons ([See Research Ethics and Governance Health Service Directive: HSD-035 Frequently Asked Questions](#)), if the purpose of the disclosure is to evaluate, manage, monitor or plan health services. This occurs, for example, when a Queensland Health employee is supported to conduct research to evaluate the impact of a new treatment/process on the HHSs discharge times and the HREC has waived the requirement of consent; or
 - a *Public Health Act 2005* approval.



Diagram 1: Pathways for disclosing confidential patient information



Related or governing legislation, policy and agreements

- *Australian Radiation Protection and Nuclear Safety Agency (ARPANSA) Code on Exposure of Humans to Ionizing Radiation for Research 2005 (Cth)*
- *Coroners Act 2003 (Qld)*
- *Defence Trade Controls Act 2012 (Cth)*
- *Gene Technology Act 2000 (Cth)*
- *Gene Technology Regulations 2001 (Cth)*
- *Guardianship and Administration Act 2000 (Qld)*
- *Hospital and Health Boards Act 2011 (Qld)*
- *Information Privacy Act 2009 (Qld)*
- *Powers of Attorney Act 1998 (Qld)*
- *Privacy Act 1988 (Cth)*
- *Prohibition of Human Cloning for Reproduction Act 2002 (Cth)*
- *Public Health Act 2005 (Qld)*
- *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 Regulations 1990 (Cth)*
- *Transplantation and Anatomy Act 1979 (Qld)*
- Australian Radiation Protection and Nuclear Safety Agency (ARPANSA). Recommendations for Limiting Exposure to Ionizing Radiation, 2003
- ARPANSA Recommendations for Limiting Exposure to Ionizing Radiation, 1995.
- ARPANSA Regulatory Impact Statement Code of Practice Exposure of Humans to Ionizing Radiation for Research Purposes
- [General Retention and Disposal Schedule for Administrative Records \(HREC and RGO administrative records\) QDAN249 v.7](#)
- [Health Sector \(Clinical Records\) Retention and Disposal Schedule QDAN 683.1](#)
- NHMRC Framework for Monitoring: Guidance for the national approach to single ethics review for multi-centre research, 2012.
- NHMRC National Certification Handbook, 2012.
- NHMRC National Statement on Ethical Conduct in Human Research, 2007, as amended from time to time



- NHMRC Research Governance Handbook: Guidance for the national approach to single ethical review, 2011
- NHMRC Guidelines to Promote the Wellbeing of Animals Used for Scientific Purposes, 2008
- NHMRC and Universities Australia; Australian Code for the Responsible Conduct of Research, 2007
- The International Society for Pharmacoepidemiology. Guidelines for Good Pharmacoepidemiology Practices, 2015
- The Therapeutic Goods Administration Note for Guidance on Clinical Safety Data Management: Definitions and Standards for Expedited Reporting, 2000
- Therapeutic Goods Administration Note for Guidance on Good Clinical Practice (CPMP/ICH/135/95)
<http://www.tga.gov.au/industry/clinical-trials-note-ich13595.htm>

Supporting documents

- Medicines Australia Clinical Trial Research Agreements
<http://medicinesaustralia.com.au/issues-information/clinical-trials/clinical-trials-research-agreements/>
- Medicines Australia Forms of Indemnity
<http://medicinesaustralia.com.au/issues-information/clinical-trials/indemnity-and-compensation-guidelines/>
- Medical Technology Association of Australia Clinical Investigation Agreement, Form of Indemnity and Compensation Guidelines <http://mtaa.org.au/policy-initiatives/clinical-investigations>
- NHMRC Standardised Participant Information and Consent Forms
<http://hrep.nhmrc.gov.au/toolbox/standardised-forms>
- Queensland Health Research Fellowship Funding Agreement Rules
- Queensland Health Researcher User Guide
- Queensland Health Schedule of fees for Commercially Sponsored Research
- Research Ethics and Governance Health Service Directive: HSD-035 Frequently Asked Questions
- 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 in Australia (October 2004)



Business area contact

Health Innovation, Investment and Research Office, Office of the Director-General.

Review

This directive will be reviewed at least every three years.

Date of last review: Reinstatement of rescinded Directive (QH-HSD-035:2013)

Supersedes: Research Ethics and Governance Directive (QH-HSD-035:2013)

Approval and Implementation

Directive Custodian

Director-General

Approval by Chief Executive

Michael Walsh, Director-General, Queensland Health

Approval date: 11 November 2016

Issued under section 47 of the *Hospital and Health Boards Act 2011*



Definitions of terms used in this directive

Term	Definition / Explanation / Details	Source
authorisation	Authorisation issued by the Department of Health and/or HHS Chief Executive or delegate to conduct research at a site. Authorisation is contingent upon the research having received HREC approval and a satisfactory research governance assessment.	Queensland Health Researcher User Guide
Australian Research Ethics Database (AU RED)	AU RED is a secure web-based Research Ethics Database that allows HREC Administrators and RGOs to store documents and report outcomes of HREC and research governance reviews. All details on the researcher's application forms are electronically uploaded into the Database.	
certified HREC	An NHMRC certified committee permitted to review multi-centre research under the National Mutual Acceptance agreement as published on the Health Innovation, Investment and Research Office website.	https://www.health.qld.gov.au/ohmr/documents/regu/nma_organisations.pdf
clinical research	As defined in section 13(1) of schedule 2 of the <i>Guardianship and Administration Act 2000</i> (Qld).	Guardianship and Administration Act 2000 (Qld)
clock day	Calendar day where a valid application, without outstanding queries, is being processed by the research ethics or governance officer. This excludes the time it takes for researchers to respond to queries.	
confidential information	Information, acquired by a person in the person's capacity as a designated person, from which a person who is receiving or has received a public sector health service could be identified, as defined in section 139 of the HHB Act.	Hospital and Health Boards Act 2011 (Qld)
coronial investigation documents	A coronial investigation document has the same meaning as 'investigation document' as defined in the <i>Coroners Act 2003</i> (Qld).	Coroners Act 2003 (Qld)
designated persons	As defined in section 139 of the HHB Act.	Hospital and Health Boards Act 2011 (Qld)
GIFTR Initiative	The Giving InFormation To Research (GIFTR) initiative gives patients admitted to certain Queensland public hospitals the option to consent for their medical information to be used in GIFTR health research. The information will only be used for GIFTR approved research projects considered to be low risk and non-interventional. No information that could identify an individual is made public, and no physical participation is required.	http://qheps.health.qld.gov.au/medical-research/access-information/giftr/default.htm
health services	As defined in section 15 of the HHB Act.	Hospital and Health Boards Act 2011 (Qld)
HHB Act	<i>Hospital and Health Boards Act 2011</i> (Qld).	Hospital and Health Boards Act 2011 (Qld)

Term	Definition / Explanation / Details	Source
Human Research Ethics Committee (HREC)	A committee registered by the NHMRC and constituted under the guidance of the NHMRC National Statement on the Ethical Conduct in Human Research 2007 (as updated) to conduct the ethical and scientific review of a human research project.	NHMRC National Statement on the Ethical Conduct in Human Research 2007
institution	Any public or private entity or agency or medical or dental facility where research/clinical trials are conducted.	Modified from the Therapeutic Goods Administration Note for Guidance on Good Clinical Practice 2000
multi-centre research	A research project undertaken by a group of institutions (or individuals) at more than one site.	http://www.nhmrc.gov.au/health_ethics/holder/index.htm#7
National Mutual Acceptance Scheme	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.	https://www.health.qld.gov.au/ohmr/html/region/mutual_accept.asp
NHMRC	National Health and Medical Research Council.	http://www.nhmrc.gov.au
Online Forms	A secure web-based platform, which integrates with AU RED, and has the ability to electronically upload research study documentation.	https://au.ethicsform.org/SignIn.aspx
PH Act approval	An approval of the Director-General under section 284 of the <i>Public Health Act 2005</i> for the person to be given health information held by Queensland Health for research purposes.	Public Health Act 2005 (Qld)
QCAT	Queensland Civil and Administrative Tribunal.	
Queensland Health	Means the Department of Health and all HHSs.	
special health matter	As defined under section 6 of schedule 2, <i>Guardianship and Administration Act 2000</i> (Qld).	Guardianship and Administration Act 2000 (Qld)
special medical research or experimental health care	As defined under section 12 of schedule 2, <i>Guardianship and Administration Act 2000</i> (Qld).	Guardianship and Administration Act 2000 (Qld)
Statewide ethics review processes	A Queensland approach to single ethical review of multi-centre research in which participating sites within Queensland public hospital have agreed to accept the scientific and ethical review of an HREC from a Queensland public health facility.	Standard Operating Procedures for Queensland Health HREC Administrators Standard Operating Procedures for Queensland Health RGOs
statutory health attorney	As defined in section 63 of the <i>Powers of Attorney Act 1998</i> (Qld).	Powers of Attorney Act 1998 (Qld)
valid application	A valid application is an AU RED status applied by the HREC or RGO when an application is deemed to	



Term	Definition / Explanation / Details	Source
	contain all required documentation.	

