Research Management Policy

Policy Statement
Queensland Health (QH) and Hospital and Health Services effectively manage the scientific and ethical review of human research and utilise a sound research governance framework to ensure that all human research is conducted in a safe and ethical manner with open and transparent use of resources.

All research and experimentation conducted in Queensland Health and Hospital Health Services will be undertaken in accordance with the legislation, policy and authoritative documents listed in this Policy:

Intent of this policy
The Research Management Policy and Implementation Standards are directed at ensuring all research conducted in QH or in collaboration with external entities is of the highest ethical and scientific standard and compliant with relevant national guidelines, codes of conduct and applicable State and Commonwealth legislation.

Scope
This policy applies to all Queensland Health and Hospital and Health Services employees (including visiting medical officers, visiting health professionals, contractors, consultants and volunteers) who propose to undertake, administrate, review and/or govern human research involving Queensland Health and Hospital and Health Services patients and staff.

Principles
Queensland Health and Health and Hospitals Services ensure all human research undertaken:

- is ethical and scientifically sound
- minimises duplication of ethical review and duplication of legal review for multi-centre research
- follows transparent and accountable research governance processes
- is adequately resourced and funded
- has prompt, sensitive and fair management of any report incidents of research misconduct
Legislative or other Authority

- ARCS Funding Agreement
- Australian Business Arts Foundation Intellectual Property and Copyright Fact Sheet
- Australian Institution of Health and Welfare Act 1987 (Cth)
- Australian Radiation Protection and Nuclear Safety Agency (ARPANSA) Code on Exposure of Humans to Ionizing Radiation for Research 2005 (Cth)
- Australian Radiation Protection and Nuclear Safety Agency (ARPANSA). Recommendations for Limiting Exposure to Ionising Radiation 2003
- Commonwealth Grant Guidelines 2009
- Coroners Act 2003
- Financial Management and Accountability Act 1997 (Cth)
- Gene Technology Act 2000 (Cth)
- Gene Technology Regulations 2001 (Cth)
- Guardianship and Administration Act 2000
- Health Services Act 1991
- Information Privacy Act 2009
- National Health and Medical Research Council (NHMRC) Framework for Monitoring: Guidance for the national approach to single ethics review for multi-centre research, 2012
- National Health and Medical Research Council (NHMRC) National Certification Handbook, 2012
- National Health and Medical Research Council (NHMRC) National Statement on Ethical Conduct in Human Research, 2007
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- National Health and Medical Research Council (NHMRC) Research Governance Handbook: Guidance for the national approach to single ethical review, 2011
- National Health and Medical Research Council (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
- NHMRC Funding Agreement
- Privacy Act 1988 (Cth)
- Prohibition of Human Cloning for Reproduction Act 2002 (Cth)
- Public Health Act 2005
- Queensland State Archives Queensland Health (Clinical Records) Retention and Disposal Schedule (QDAN 546 v.3)
- Research Involving Human Embryos Act 2002 (Cth)
- Research Involving Human Embryos and Prohibition of Human Cloning Act 2003
- Therapeutic Good Administration (TGA) Access to Unapproved Therapeutic Goods – Clinical Trials in Australia (October 2004)
- Therapeutic Good Administration (TGA) Note for Guidance on Good Clinical Practice (CPMP/ICH/135/95)
- Therapeutic Goods Act 1989 (Cth)
- Therapeutic Goods Regulations 1990 (Cth)
- Transplantation and Anatomy Act 1979

Related Policy or Documents

Code of Conduct - Workplace Ethics, Conduct and Behaviour QH-POL-113:2011

Queensland Health Credentialing and Scope of Practice for Medical Practitioners and Dentists in Queensland Health Policy QH-POL-330:2012

Queensland Health HR Policy Indemnity for Employees and Other Persons QH-POL-152:2010
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Queensland Health HR Policy Indemnity for Queensland Health Medical Practitioners I2 QH-POL-153:2009

Queensland Health Intellectual Property Policy QH-POL-009:2010


Queensland Health Respecting Your Privacy: What Happens to Your Personnel Information

Queensland Health Retention and Disposal of Clinical Records QH-POL-280:2005

Queensland Health Standard Operating Procedures for Human Research Ethics Committees 2012

Queensland Health Standard Operating Procedures for Research Governance 2012

Supporting Documents
The following Implementation Standards specify the requirements that should be met to support the intent of the policy.
- Ethical and Scientific Review of Research
- Consent, access, use of confidential health information/data
- Research Governance
- Managing conflicts of interest
- External research funding and infrastructure support

Review
This policy and standards will be reviewed annually.

Triggers for a review outside of this schedule include:
- Changes in national and or international guidelines for research ethics and governance.
- Changes to corporate and or research governance in Queensland Health;
- Changes to the Queensland Health information system (AU RED) for research ethics management and on-line forms.

Date of Last Review: 2012

History

<table>
<thead>
<tr>
<th>Date of new / revised policy</th>
<th>Amended to</th>
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<tbody>
<tr>
<td>June 2012</td>
<td>Version 1.2 – Changes to principles, added minimises duplication of legal review for multi-centre research, updated guidance, regulatory and legislative requirements.</td>
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Supersedes:

Policy Custodian
Director, Research Ethics and Governance Unit, Office of Health and Medical Research.

Responsible Executive Management Team member
Chief Executive Officer, Centre for Healthcare Improvement.

Approval and Implementation

Approving Officer
Chief Executive Officer, Centre for Healthcare Improvement

Approval Date 10 June 2012
Implementation Date 29 June 2012

Glossary of Terms used in this policy and supporting documents

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<tr>
<th>Term</th>
<th>Definition</th>
<th>Source</th>
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<tr>
<td>Authorisation</td>
<td>Authorisation issues by the QH and Hospital and Health Services CEO or delegate to conduct research at the site. Authorisation is contingent upon receiving the research having HREC approval and a completed site-specific assessment.</td>
<td>QH Researcher User Guide</td>
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<td>Australian Research Ethics Database (AU-RED)</td>
<td>AU-RED is a secure web-based Research Ethics Database that allows researchers to complete and submit a NEAF application online. All details on the NEAF submission will be electronically downloaded into the Research Ethics Database (AU-RED).</td>
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<td>Central Coordinating Service (CCS)</td>
<td>A service provided by the Office of Health and Medical Research 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.</td>
<td>NHMRC National Statement on the Ethical Conduct in Human Research 2007</td>
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<td>HREC</td>
<td>A committee constituted under the guidance of the NHMRC National Statement on the Ethical Conduct in Human Research 2007 to conduct the ethical and scientific review of a human research protocol.</td>
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<td>Indemnity</td>
<td>A contractual promise by one party to protect the other party from and against certain specified actions, claims or losses. If the research project is a sponsored clinical trial, the sponsor or CRO</td>
<td>QGIF</td>
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<tr>
<td>Institution</td>
<td>Any public or private entity or agency or medical or dental facility where clinical trials are conducted.</td>
<td>TGA Note for Guidance on Good Clinical Practice 2000</td>
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<td>Multi-centre Research</td>
<td>A research project undertaken by a group of institutions (or individuals) at one or more sites.</td>
<td><a href="http://www.nhmrc.gov.au/health_ethics/home/index.htm">http://www.nhmrc.gov.au/health_ethics/home/index.htm</a> #7</td>
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<td>Clinical Trial Research Agreement (CTRA)</td>
<td>A written agreement between one or more parties, which sets out the responsibilities of each party. Queensland Health, in collaboration with interstate health departments, Victorian Managed Insurance Authority (VMIA) and MA, has developed a set of standard Clinical Trial Research Agreements (CTRA) to be used by Hospitals/Institutions. The CTRAs contain common, standard provisions. The CTRAs should, in most cases, obviate the need for Hospitals/Institutions to obtain extensive legal advice in relation to a Clinical Trial Research Agreement.</td>
<td>VMIA Guidelines for Clinical Trials For Victorian Public Hospitals 2009</td>
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<td>Medicines Australia Clinical Trial Research Agreement (MA CTRA)</td>
<td>A CTRA between the Hospital/Institution and the Sponsor – including, where relevant, a Commercial Sponsor.</td>
<td>VMIA Guidelines for Clinical Trials For Victorian Public Hospitals 2009</td>
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<td>MA Corporate Research Organisation (CRO) CTRA</td>
<td>A CTRA to be used where an entity/company that is not an Australian resident wishes to initiate a clinical trial and engages a CRO (that is an Australian entity) to act as the local Sponsor for the purposes of the CTN application. The CRO becomes and assumes all responsibilities and obligations that attach to a local Sponsor.</td>
<td>VMIA Guidelines for Clinical Trials For Victorian Public Hospitals 2009</td>
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<td>MA Collaborative Research Group (CRG) CTRA</td>
<td>A CTRA to be used when a collaborative/cooperative research group is the sponsor of the clinical trial.</td>
<td>VMIA Guidelines for Clinical Trials For Victorian Public Hospitals 2009</td>
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