



Queensland
Government
Queensland Health

RESEARCH MANAGEMENT POLICY
&
FRAMEWORK
2008

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Policy

This policy provides the framework and standards for the scientific and ethical review of human research, research governance responsibilities and other relevant processes for the management of research undertaken within or in collaboration with Queensland Health. All research and experimentation conducted in Queensland Health will be undertaken in accordance with the ethical principles articulated in the National Health and Medical Research Council (NHMRC) “*National Statement on Ethical Conduct in Human Research*” 2007 and the NHMRC and Universities Australia “*Australian Code for the Responsible Conduct of Research*” 2007.

Framework

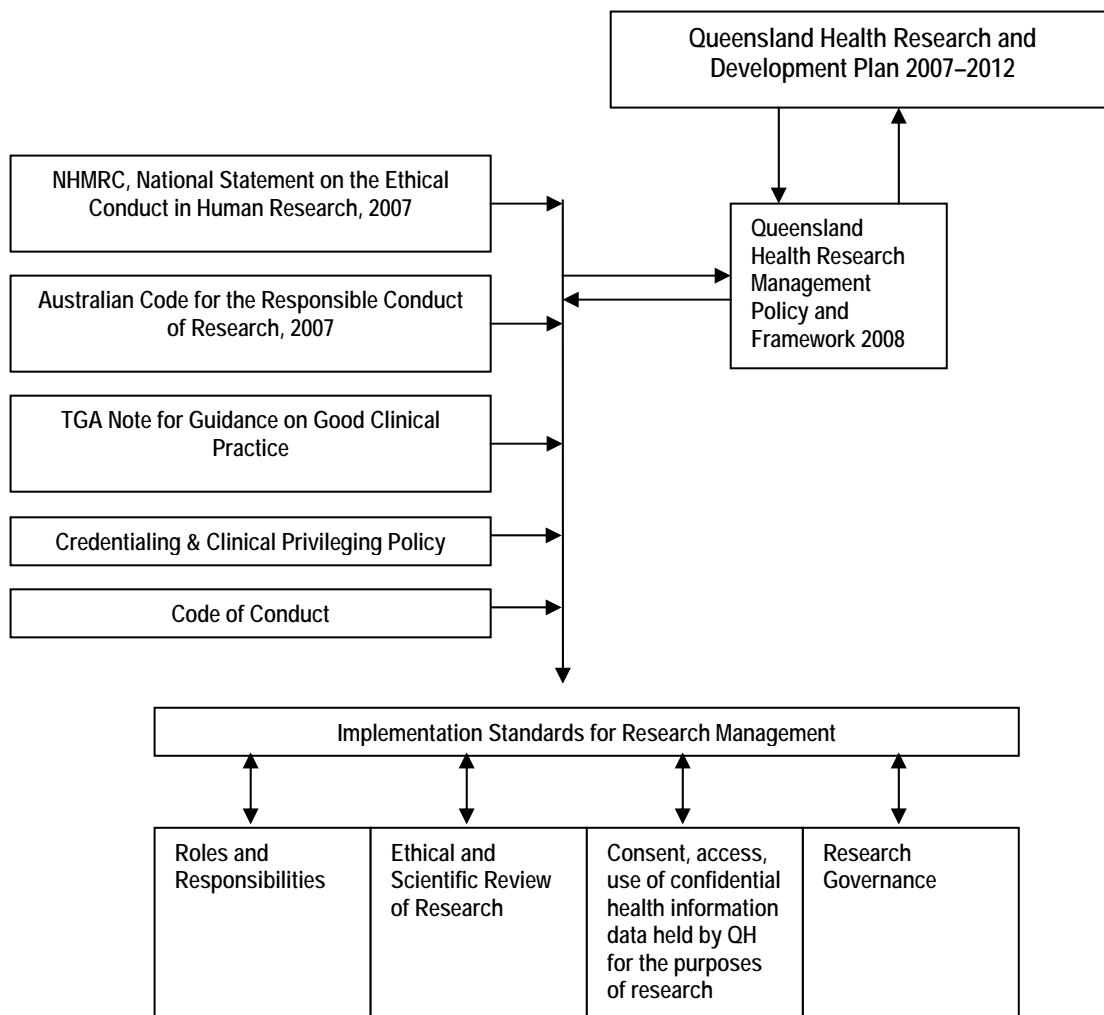
The Research Management Policy and Framework 2008, are the policies, procedures and accountabilities that are directed at ensuring all research conducted in QH or in collaboration with external entities is of the highest ethical and scientific standard and compliant with relevant national guidelines, codes of conduct and applicable State legislation.

Fundamental elements to Research Ethics and Governance

1. All human research conducted in QH will have undergone ethical and scientific review.
2. The Principal Investigator will be responsible for the safe and ethical conduct of the research and the actions of the research team.
3. All costs and resources associated with the conduct of research are to be accounted for in the Site Specific Assessment and reimbursed to the participating Queensland Health District.
4. Where practical, duplication of the ethical and scientific review process for multi-centre research will be minimised.
5. All research misconduct will be managed through due process as outlined in the NHMRC Australian Code for the Responsible Conduct of Research 2007

Policy Structure

The diagram indicates the configuration of the policy and supporting documentation for the Queensland Health Research Ethics Governance Policy.



Responsible Business Area: Research Ethics and Governance Unit, Office of Health and Medical Research.

Policy Sponsor: Chief Executive Officer, Centre for Healthcare Improvement.

Policy Contact: Research Ethics and Governance Unit Ph 32240034 Email: REGU@health.qld.gov.au

Further Information see links (below)

Policies and relevant Implementation Standards are to be used in conjunction with the Guidelines, Procedures, Work instructions, Forms, related Legislation and Documents.

Data Systems and Procedures	Related Documents and Information Sites
On-line QH National Ethics Application Form (NEAF)	<p><u>National Guidelines</u></p> <p>NHMRC “National Statement on Ethical Conduct in Human Research” 2007.</p>
On-line Queensland Health Site Specific Assessment (SSA)	<p>NHMRC and Universities Australia “Australian Code for the Responsible Conduct of Research” 2007.</p> <p>TGA Note for Guidance on Good Clinical Practice (CPMP/ICH/135/95).</p>
On-line Public Health Act 2005 Application for access to health information (PHA)	<p>NHMRC Guidelines to Promote the Wellbeing of Animals Used for Scientific Purposes (2008).</p> <p><u>Corporate Governance Policy and Guidelines</u></p> <p>Financial Administration and Audit Act 1977 & Financial Management Standard 1997.</p>
Queensland Health Research Ethics Database (AU-RED)	<p>Queensland Health Researcher User Guide 2008.</p> <p>Queensland Health Standard Operating Procedures for Human Research Ethics Committees 2008.</p> <p>Queensland Health Standard Operating Procedures for Research Governance August 2008.</p>

The following Implementation Standards specify the requirements that must be met to support the intent of the policy and framework:

1. **Roles and Responsibilities**
2. **Ethical and Scientific Review of Research**
3. **Consent, access, use of confidential health information / data for the purposes of research**
4. **Research Governance**

1. ROLES AND RESPONSIBILITIES

Implementation Standard 1 applies to all Queensland Health employees and agents, including the Centre for Healthcare Improvement, Queensland Health Corporate Office, Statewide Services and Health Districts.

1. Purpose:

This Standard describes the mandatory auditable requirements regarding roles and responsibilities for research ethics and research governance.

2. Scope:

This Standard applies to:

All Queensland Health employees (permanent, temporary and casual), agents of the department (organisations and individuals), including employees, non QH research collaborators, sponsors and agents (including Visiting Medical Officers, visiting health professionals, contractors, consultants and volunteers) who propose to undertake human research involving Queensland Health patients, staff, facilities and / or resources.

3. Authorising Policy:

Queensland Health Research Management Policy and Framework 2008

4. Review:

This Standard will be reviewed annually and revised if there are policy and process changes for

- Corporate and research governance in Queensland Health;
- Queensland Health information system (AU RED) for research ethics management and on-line forms.

5. Supersedes:

Queensland Research Management Policy 2004 (No 24938).

6. Business Contact:

Any requests for further information or clarification regarding this Standard should be referred to the Research Ethics and Governance Unit, (REGU), Office of Health and Medical Research via email REGU@health.qld.gov.au.

7. Further Information, see links below:

The links below provide additional information relating to the roles and responsibilities process and related topics.

Data Systems and Forms	Related Documents and Information Sites
On-line National Ethics Application Form (NEAF)	<p><u>National Guidelines</u></p> <p>NHMRC “National Statement on Ethical Conduct in Human Research” 2007.</p>
On-line Queensland Health Site Specific Assessment form (SSA)	<p>NHMRC and Universities Australia “Australian Code for the Responsible Conduct of Research” 2007.</p> <p>TGA Note for Guidance on Good Clinical Practice (CPMP/ICH/135/95).</p> <p>TGA Access to Unapproved Therapeutic Goods – Clinical Trials in Australia October 2004.</p>
On-line Public Health Act 2005 application for access to health information (PHA)	<p>ARPANSA Recommendations for Limiting Exposure to Ionising Radiation 2003.</p> <p>NHMRC Guidelines to Promote the Wellbeing of Animals Used for Scientific Purposes 2008.</p>
Queensland Health Research Ethics Database (AU-RED)	<p><u>Corporate Governance Policy</u></p> <p>Queensland Health Credentialing and Scope of Practice Standard.</p> <p>Queensland Health Guidance for Site Specific Assessment 2008.</p> <p>Queensland Health Intellectual Property Policy 2006.</p> <p>Queensland Health Integrated Risk Management Policy 2008.</p> <p>Queensland Health Researcher User Guide 2008.</p> <p>Queensland Health Standard Operating Procedures for Human Research Ethics Committees 2008.</p> <p>Queensland Health Standard Operating Procedures for Research Governance August 2008.</p>

8. Roles and Responsibilities:

The following roles and responsibilities apply with respect to this Implementation Standard. The criteria specify mechanisms for measuring performance against the responsibilities.

Title /Role	Accountabilities	Criteria
Director-General	<p>The Director General is accountable for the overall leadership, stewardship and performance of the Department and the use of resources in the conduct and governance of research. The Director General has a number of statutory responsibilities to ensure systems are in place to manage the safe and ethical conduct of research. These include:</p> <ul style="list-style-type: none"> • assessing the ethical and scientific quality of all research being conduct in QH or in collaboration with external entities; • assessing the suitability of QH sites/facilities to support the conduct and completion of research; • having research governance processes in place to ensure all legal and financial risk are identified and managed; • ensuring patient health information and confidentiality is maintained; and • monitoring the conduct of research being undertaken in QH facilities. 	<p>Endorsed policy and implementation standards are published on the internet.</p> <p>Regularly review research priorities for Queensland Health.</p>
Chief Executive Officer, Centre for Healthcare Improvement	<p>This position is accountable and responsible for:</p> <ul style="list-style-type: none"> • providing leadership in research and development; • publishing a report and measurement of research activity in Queensland Health; and • ensuring all employees are aware of and comply with the Queensland Health the Research Management Policy and Framework 2008 (No 24938) and its Implementation Standards. 	<p>Research activity incorporated into the Integrated Performance Reporting.</p> <p>Communicate, monitor and review management of research activity.</p>

Title /Role	Accountabilities	Criteria
Senior Director, Queensland Health Office of Health and Medical Research	<p>This position is accountable and responsible for:</p> <ul style="list-style-type: none"> • Overseeing the development and revision of the Queensland Health Research Management Policy and Framework 2008 (No 24938) and its Implementation Standards; • overseeing the ethical conduct of research; and • providing advice and direction on health and medical research priorities. 	<p>Research Management Policy and Framework Policy are implemented across all QH Districts.</p>
Research, Ethics and Governance Unit	<p>This Unit is accountable and responsible for: Undertake annual review of Queensland Health Research Management Policy and Framework 2008 (No 24938) and its Implementation Standards in line with national guidelines and relevant legislative requirements.</p>	<p>Research Management Policy and Framework is reviewed annually and revised if there are policy and process changes.</p> <p>Master registry is maintained (Research Ethics Database – AU RED) of research protocols reviewed and approved by QH Human Research Ethics Committees (HREC).</p>
District CEO	<p>This position is accountable and responsible for:</p> <ul style="list-style-type: none"> • providing support for the implementation of the of Queensland Health Research Management Policy and Framework 2008 (No 24938) and its Implementation Standards in the District • monitoring research being conducted at sites in the District is compliance with the Implementation Standards; • ensuring streamlined administrative processes for research governance within the District; • having in place systems for the management of complaints about research, including research misconduct and fraud; and • allocating funds for education and training opportunities of HREC members. 	<p>Annual report of research activity in District.</p> <p>Annual report of research complaints, including research misconduct and fraud.</p> <p>Annual Report on the proportion of protocols approved in less than 60 calendar days.</p> <p>Annual report on the proportion of Site Specific Assessments completed in less than 25 calendar days.</p> <p>Annual report on training attended by District HREC members.</p>

Title /Role	Accountabilities	Criteria
Research Directors and/or Managers responsible for Research Ethics and Governance	<p>This position is accountable and responsible for:</p> <ul style="list-style-type: none"> • providing support and advice to the District Executive, researchers and research sponsor in accordance with the Queensland Health Research Management Policy and Framework 2008 (No 24938) and its Implementation Standards; • facilitating a culture of safe and high quality research through the promotion and awareness of the of the National Statement and Code; • ensuring administrative systems are in place to monitor, review and evaluate research being conducted in the District; • facilitate and coordinate the preparation of the annual research report for the District; • monitoring District research activity in line with conditions of approval; and • participating in the development of systems to improve the conduct and governance of research. 	<p>Prepare annual report of District research activity.</p> <p>Prepare research revenue report for the Office of the Chief Scientist.</p> <p>Prepare the biannual ABS Research Report.</p>
District HREC Coordinator and Governance Officers	<p>This position is accountable and responsible for:</p> <ul style="list-style-type: none"> • entering all research protocols reviewed by a QH District HREC into AU RED; • providing secretariat support for a HREC; • providing administrative support for Site Specific Assessment and authorisation of research; and • Coordinate the annual reporting of HREC activity to the NHMRC. 	<p>Accurate data entry into AU RED.</p> <p>Preparation of annual NHMRC HREC activity report.</p>
Principal Investigators and Researchers	<p>This position is accountable and responsible for:</p> <ul style="list-style-type: none"> • conducting research in accordance with national guidelines and the Queensland Health Research Management Policy and Framework 2008 (No 24938) and its 	<p>Submit all protocols on QH Online NEAF for uploading into AU-RED or imported into AURED in xml format from the NHMRC NEAF.</p> <p>Complete a Site Specific Assessment and obtain</p>

	<p>Implementation Standards;</p> <ul style="list-style-type: none"> • ensuring research practices reflect current professional (ethical and legal) standards for research, including reporting conflicts of interest; • responding promptly to reporting and monitoring standards, including adverse events, complaints and clinical incidences; • maintaining good research records and making records available for review; • ensuring compliance with legislative and policy requirements for patient contact, consent and confidentiality of patient information; • only conducting clinical intervention studies with the essential approved credentialing privileges and experience; and • registering all clinical trials on a publicly accessible clinical trial registry, prior to the commencement of the clinical phase of the trial. 	<p>District authorisation prior to commencement of research.</p> <p>Provide scheduled progress and final reports provided to the HREC and Governance Officer as required from authorisation of research.</p> <p>Prepare application for access to information / data held by the Department for use in research where required.</p> <p>Only conduct research that is consistent with professional privileges and training.</p> <p>Register all clinical trials on the Australian New Zealand Clinical Trials Registry (ANZCTR) or on another authorised clinical trial registry.</p>
<p>Project Liaison Officer/s and Clinical Trials Coordinators</p>	<p>This position is accountable and responsible for:</p> <ul style="list-style-type: none"> • liaising between the Principal Investigator and District Human Research Ethics Committee and Research Governance Office/r; • facilitating arrangements for the research team to access the District's resources and support as agreed in the research contract and identified on the Site Specific Assessment form; and • liaising with the Principal Investigator and research sponsor regarding the management, monitoring and financial reporting of the research project. 	<p>All documentation and records associated with external research partners are maintained and auditable.</p>

<p>Research supervisors</p>	<p>This position is accountable and responsible for:</p> <ul style="list-style-type: none"> • liaising between the student and the student liaison officer if the supervisor is not a Qld Health employee; • fulfilling a supervisory role and take responsibility for the student and act as a primary source of guidance to the student; • ensuring work submitted by research students and trainees is their own and that their data are valid; • advising each trainee of applicable government and institutional guidelines for the conduct of research Intellectual Property rights and obligations; • ensuring students are familiar with Queensland Health Student Orientation Requirements. (Student Health Professionals' Clinical Placement or Fieldwork Orientation; and • ensuring tertiary students are familiar and compliant with the Student Placement Deed (if applicable) between Queensland Health and the Tertiary Education Provider through which they are undertaking their research program. 	<p>All students will have a supervisor.</p> <p>Students will liaise with a student liaison person if the supervisor is not a Queensland Health employee.</p> <p>Orientation procedures, including signing and submitting the task checklist to the relevant HREC, will be completed.</p>
<p>Human Research Ethics Committee (HRECs) — including HREC Scientific Sub-Committees</p>	<p>This position is accountable and responsible for :</p> <ul style="list-style-type: none"> • conducting ethical and scientific review of research proposals in line with the NHMRC National Guidelines and Queensland Health Research Management Policy and Framework 2008 (No 24938) and its Implementation Standards. 	<p>Research protocols are reviewed in accordance with the NHMRC standards and guidelines.</p>

2. ETHICAL AND SCIENTIFIC REVIEW OF RESEARCH

Implementation Standard 2 applies to all Queensland Health employees and agents, including the Centre for Healthcare Improvement, Queensland Health Corporate Office, Statewide Services and Health Districts.

1. Purpose:

This Standard describes the mandatory requirements regarding the ethical and scientific review of research being conducted in Queensland Health. This standard uses terms and concepts defined in the Queensland Health Research Management Policy and Framework 2008.

2. Scope:

This Standard applies to

All Queensland Health employees (permanent, temporary and casual), agents of the department (organisations and individuals), including employees, non QH research collaborators, sponsors and agents (including visiting medical officers, visiting health professionals, contractors, consultants and volunteers) who propose to undertake human research involving Queensland Health patients and staff.

3. Authorising Policy:

Queensland Health Research Management Policy and Framework 2008.

4. Review:

This Standard will be reviewed annually and revised if there are policy and process changes for:

- Corporate and research governance in Queensland Health; and
- Queensland Health information system for research ethics governance and on-line forms.

5. Supersedes:

Queensland Research Management Policy 2004 (No 24938).

6. Business Contact:

Any requests for further information or clarification regarding this Standard should be referred to the Research Ethics and Governance Unit, (REGU), Office of Health and Medical Research via email REGU@health.qld.gov.au

7. Further Information, see links below:

The links below provide additional information relating to the ethical and scientific review of research and related topics.

Data Systems and Forms	Related Documents and Information Sites
<p>On-line National Ethics Application Form (NEAF)</p> <p>On-line Queensland Health Site Specific Assessment form (SSA)</p> <p>On-line Public Health Act 2005 Application for access to health information (PHA)</p> <p>Queensland Health Research Ethics Database (AU-RED)</p>	<p><u>National Guidelines</u></p> <p>NHMRC “National Statement on Ethical Conduct in Human Research” 2007.</p> <p>NHMRC and Universities Australia “Australian Code for the Responsible Conduct of Research” 2007.</p> <p>TGA Note for Guidance on Good Clinical Practice (CPMP/ICH/135/95).</p> <p>TGA Access to Unapproved Therapeutic Goods – Clinical Trials in Australia (October 2004).</p> <p>ARPANSA Recommendations for Limiting Exposure to Ionising Radiation 2003.</p> <p>NHMRC Guidelines to Promote the Wellbeing of Animals Used for Scientific Purposes 2008.</p> <p>Therapeutic Goods Act 1989 (Cth).</p> <p>Gene Technology Act 2000 and the Gene Technology Regulations 2001.</p> <p><u>Corporate Governance Policy</u></p> <p>Queensland Health Standard Operating Procedures for Human Research Ethics Committees 2008.</p> <p>Queensland Health Standard Operating Procedures for District Research Governance 2008.</p> <p>Queensland Health Guidance in Using the Standard Site Specific Assessment Form 2008.</p> <p>Queensland Health Researcher User Guide 2008.</p> <p>Queensland Health Intellectual Property Policy 2006.</p> <p>Queensland Health Credentialing and Scope of Practice Standard.</p> <p>Queensland Health Integrated Risk Management Policy 2008.</p>

8. Ethical and Scientific Review of Human Research:

- All human research as defined by the NHMRC, conducted in or accessing patients, data, facilities, and or staff in Queensland Health must, at a minimum be reviewed and approved by a Human Research Ethics Committee (HREC) or an alternative process if Low and Negligible Risk Research.
- Any requests directed to a researchers, made by a HREC for additional information or amendments, must be provided in a timely manner to ensure prompt review and resolution. Delays in providing information to a HREC may result in a protocol being withdrawn from a HREC review.
- All research protocols submitted to a Queensland Health HREC must be presented on a QH Online NEAF form or NHMRC NEAF in xml format.
- Only research and experimental protocols, approved by a HREC, with a completed Site Specific Assessment (SSA) form will be considered for authorisation.
- For Low and Negligible Risk Research, applicants should contact their local HREC office to discuss the proposed research and identify whether the project is suitable for an alternative review other than a HREC review.
- For Low and Negligible Risk Research involving only the risk of inconvenience, a QH site may choose to grant exemption from full HREC review and offer an alternative review process.
- Applicants whose proposals are considered to be Low and Negligible Risk Research are to complete the checklist and application template and seek authorisation through the relevant channels of review.
- At the discretion of the District, some Low and negligible Risk Research may require a Site Specific Assessment if District resources are required to support the conduct and completion of the research at that site.

9. Ethical and Scientific Review of Animal Research:

- Queensland 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 all research on animals conforms to the Commonwealth, National and State guidelines, policies and legislation relating to the ethical conduct of animal research.
- Facilities lacking Animal Ethics Committees (AEC), but undertaking animal research, must 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 must comply with the regulatory requirements for animal research as set by the QH AEC or collaborating organisations (e.g. Universities / Research institutions).

10. Regulation of Gene Technologies and Related Therapies:

- Queensland Health researchers are required by law to abide by the Commonwealth scheme for the regulation of Genetically Modified Organisms (GMOs) in Australia as defined in the Gene Technology Act 2000 and the Gene Technology Regulations 2001.
- Queensland Health facilities in which researchers are using gene technology or undertaking dealings' (as that term is defined in the legislation) must be accredited and maintain, or have an established link with, a properly constituted Institutional Biosafety Committee (IBC) within a collaborating organisation.
- The research must be assessed and comply with recommendations made by the NHMRC Cellular Therapies Advisory Committee (CTAC) and the IBC prior to this review and approval from a HREC.
- All research protocols involving gene therapy and related gene technologies including xenotransplantation must be submitted to a HREC for review.

11. Ionising Radiation:

- All research involving any form of radiation must 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 must be provided with a written report from an accredited medical physicist.
- Individuals using ionizing radiation must hold a valid 'License to Use', which can be obtained from the Queensland Health Radiation Safety Unit via the Institution's Radiation Safety Officer.

12. Use of Approved and Unapproved Medicines and Medical Devices:

- Research in Queensland that involves the use of approved or unapproved medicines, medical devices, blood, tissues and chemicals must be compliant with the legislation, regulations and guidelines of the Therapeutic Goods Administration.

13. Risk management :

- Risk assessment and monitoring for industry sponsored and investigator initiated research will include review by the HREC of local Serious Adverse Events (SAE) or serious unexpected events and will be coordinated by the Principal Investigator.
- Risk assessment and monitoring for industry sponsored and investigator initiated research will include review by the HREC of Data Safety and Monitoring Board (DSMB) reports and will be coordinated by the Principal Investigator.
- If a DSMB has not been formed for the submitted study then the Principal Investigator must stipulate in their HREC application whether an interim safety analysis is required for the study. If it is not required then the Principal Investigator must provide a rationale.

- In the absence of a DSMB, the Principal Investigator must outline to the HREC the process for ensuring adequate independent monitoring of efficacy and safety for the duration of their study.
- For investigator initiated studies a risk assessment must be undertaken and comply with the Queensland Health Integrated Risk Management Policy.
- The Principal Investigator must be cognisant of the TGA requirement for reporting SAEs and any unexpected serious adverse events.
- Risk assessment and monitoring for industry sponsored research must include periodical sponsor monitoring, inspections by Regulatory Bodies (both national and international) as well as sponsor initiated internal audits.
- Risk assessment and monitoring risk assessment for investigator initiated studies may include inspections by a designated and appropriately skill District research governance officer.

14. Review of Multicentre Research:

- On the commencement of a single review process, when dealing with a multicentre research (MCR) project, a designated Lead HREC will conduct a full ethical and scientific review of a multicentre research protocol. The site-specific aspects of this protocol will be conducted outside the business of the HREC by the researcher in accordance with the research governance processes of the District or site.
- At each site where a MCR project is being undertaken, a Site Specific Assessment (SSA) must be conducted to determine what resources are required for the support and successful completion of the research at that site. This will include identification of actual and 'in kind' cost associated with the conduct of the research at each site.
- All MCR protocols will have a co-ordinating investigator who will coordinate the
 - HREC review of the protocol and or any amendments,
 - progress reporting requirements as specified by the Lead HREC,
 - reporting of any serious adverse events, and
 - communication with all the site principal investigators, funders and sponsors.
- Without compromising the review process, a benchmark of 60 calendar days for completion of the ethical and scientific review process is desirable. The review clock does not include the time taken for the investigator to attend to the requested amendments or provide additional information.
- Without compromising the research governance process, a benchmark of 25 calendar days for completion of the research governance processes including contract management is desirable. The review clock does not include the time taken for the investigator to attend to the requested amendments or provide additional information.

3. CONSENT, ACCESS AND USE OF CONFIDENTIAL HEALTH INFORMATION FOR THE PURPOSE OF RESEARCH

Implementation Standard 3 applies to all Queensland Health employees and agents, including the Centre for Healthcare Improvement, Queensland Health Corporate Office, Statewide Services and Health Districts.

1. Purpose:

This Standard describes the mandatory requirements regarding consent, access and use of confidential health information held by the department for the purpose of research. This standard uses terms and concepts defined in the Queensland Health Research Management Policy and Framework 2008.

2. Scope:

This Standard applies to:

All Queensland Health employees (permanent, temporary and casual), agents of the department (organisations and individuals), including employees, non QH research collaborators, sponsors and agents (including visiting medical officers, visiting health professionals, contractors, consultants and volunteers) who propose to undertake human research involving Queensland Health patients and staff.

3. Authorising Policy:

Queensland Health Research Management Policy and Framework 2008.

4. Review:

This Standard will be reviewed annually and revised if there are policy and process changes for

- Corporate and research governance in Queensland Health;
- Queensland Health information system for research ethics governance and on-line forms.

5. Supersedes:

Queensland Research Management and Framework 2004 (No 24938).

6. Business Contact:

Any requests for further information or clarification regarding this Standard should be referred to the Research Ethics and Governance Unit, (REGU), Office of Health and Medical Research via email REGU@health.qld.gov.au.

7. Further Information, see links below:

The links below provide additional information relating to the access and use of health information for the purposes of research and related topics.

Data Systems and Forms	Related Documents and Information Sites
On-line National Ethics Application Form (NEAF)	<p><u>National Guidelines and Relevant legislation</u></p> <p>NHMRC “National Statement on Ethical Conduct in Human Research” 2007.</p>
On-line Queensland Health Site Specific Assessment form (SSA)	<p>NHMRC and Universities Australia “Australian Code for the Responsible Conduct of Research” 2007.</p> <p>Health Services Act 1991.</p> <p>Public Health Act 2005.</p>
On-line Public Health Act 2005 Application for access to health information (PHA)	<p>Privacy Act 1988 (Cth).</p> <p><u>Corporate Governance Policy and Guidelines.</u></p> <p>Part 7 Confidential Guidelines: http://QueenslandHealtheps.health.qld.gov.au/privacy/docs/Confidentiality_Guidelines.pdf.</p>
Queensland Health Research Ethics Database (AU-RED)	<p>Information Privacy for Queensland Health Staff: http://QueenslandHealtheps.health.qld.gov.au/privacy/docs/Info_Privacy_Queensland_Health_staff.pdf.</p> <p>Respecting your Privacy: What Happens to Your Personal information. http://QueenslandHealtheps.health.qld.gov.au/privacy/docs/Respecting_Your_Privacy.pdf.</p>
	<p>Information Standard No 42A: Information Privacy for the Queensland Department of Health.</p>
	<p>Information Standard 42A; Information Privacy Guidelines.</p>
	<p>Queensland Health Retention and Disposal of Clinical Records Policy.</p>
	<p>Queensland State Archives Queensland Health (Clinical Records) Retention and Disposal Schedule (QDAN 546 v.3).</p>
	<p>Queensland Health Researcher User Guide 2008.</p>

8. Obtaining Consent for Research:

- Researchers when seeking consent must:
 - Never use coercion or pressure with participants;
 - Renegotiate the consent where projects have an extended duration; and
 - when there are significant amendments or the protocol is complex.
- Consent to participate in a research study must comply with all the principles and guidelines for consent as described in the National Statement on the Ethical Conduct of Human Research 2007.
- Only a Human Research Ethics Committee can grant waiving of consent for the use of personal information in the conduct of research.
- Researchers are to reimburse the participants for reasonable cost of participating in research and disclose any conflict of interest to participants.

9. Unspecified Consent for Future Use of Data and Tissue:

- Studies that seek to have unspecified use of personal information (including information from tissue) must detail the purpose and relationship of the information to the existing project in terms of the future use in the consenting process in the review protocol.
- Consent must be sought to access this additional information from data or tissue unless the need for consent has been waived by the Human Research Ethics Committee (HREC).

10. Use of Personal Information from Databanks:

- Databanks include any collection of personal information that may be used for the purposes of research. Use of databanks must follow the principles and guidelines for databanks as described in the National Statement on the Ethical Conduct of Human Research 2007.
- Data sourced from databanks for the purposes of a research project may be subject to the research provisions of the Public Health Act 2005 Chapter 6, Part 4, Division 2, s281 – s284.

11. Access and Use of Confidential Information for the Purposes of Research:

- When researchers require access and use of confidential information held by Queensland Health for the purposes of research, the provisions of the Public Health Act 2005 Chapter 6, Part 4, Division 2, s281 – s284 must be considered.

12. Application to Access Confidential Information held by QH for the Purposes of Research:

- Prior to commencing research, the researcher must
 - Seek Human Research Ethics Committee approval for the protocol; and
 - Discuss data requirements with the data custodian (contact details available on the Internet).

- The applicant when requesting information from the data custodian must clearly indicate the
 - type of data (e.g. data fields);
 - detail of data time interval; and / or
 - duration of access.
- On completion of the above two steps the applicant proceeds to make formal application under the provisions of the Public Health Act 2005. Contact the Research Ethics and Governance Unit for details on the application process.
- All information about an application approved by the Chief Executive (Director General) or delegate is kept on a Research Registry by the Office Health and Medical Research in accordance with Division 3 s288 Public Health Act 2005.
- Queensland Health may charge a fee for the retrieval of health information for the purposes of research. The data custodian will have details of these potential costs.

13. Access to Tissue Samples held by Clinical and Statewide Services:

- Researchers requiring access to tissue held by Queensland Health, will be required to make an application to the Clinical and Statewide Service (CaSS) Research Committee http://Queensland Health/eps.health.qld.gov.au/Queensland Health/css/research/cass_rc.htm, prior to making application under the *Public Health Act 2005*. The application form and researcher information may be found on <http://www.health.qld.gov.au/cpic/content/access.asp>

14. Storage of Confidential Information:

- All patient information relating to a research project must comply with the QH Retention and Disposal Schedule and in line with National Statement on the Ethical Conduct of Human Research 2007 and Australian Code for the Responsible Conduct of Research (2007).

4. RESEARCH GOVERNANCE

Implementation Standard 4 applies to all Queensland Health employees and agents, including the Centre for Healthcare Improvement, Queensland Health Corporate Office, Statewide Services and Health Districts.

1. Purpose:

This Standard describes the mandatory requirements regarding the standards, requirements, procedures and processes for meeting research governance responsibilities which include financial management, contract management and intellectual property. This standard uses terms and concepts defined in the Queensland Health Research Management Policy and Framework 2008.

2. Scope:

This Standard applies to

All Queensland Health employees (permanent, temporary and casual), agents of the department (organisations and individuals), including employees, non QH research collaborators, sponsors and agents (including visiting medical officers, visiting health professionals, contractors, consultants and volunteers) who propose to undertake human research involving Queensland Health patients and staff.

3. Authorising Policy:

Queensland Health Research Management Policy and Framework 2008.

4. Review:

This Standard will be reviewed annually and revised if there are policy and process changes for

- Corporate and research governance in Queensland Health;
- Queensland Health information system for research ethics governance and on-line form.

5. Supersedes:

Queensland Research Management Policy 2004 (No 24938).

6. Business Contact:

Any requests for further information or clarification regarding this Standard should be referred to the Research Ethics and Governance Unit, (REGU), Office of Health and Medical Research via email REGU@health.qld.gov.au

7. Further Information, see links below:

The links below provide additional information relating to research governance.

Data System and Forms	Related Documents and Information Sites
<p>On-line National Ethics Application Form (NEAF)</p> <p>On-line Queensland Health Site Specific Assessment form (SSA)</p> <p>On-line Public Health Act 2005 Application for access to health information (PHA)</p> <p>Queensland Health Data Systems Research Ethics Database (AU-RED)</p>	<p><u>National Guidelines and Relevant Legislation</u></p> <p>NHMRC “National Statement on Ethical Conduct in Human Research” 2007.</p> <p>NHMRC and Universities Australia “Australian Code for the Responsible Conduct of Research” 2007.</p> <p>Financial Administration and Audit Act 1977 & Financial Management Standard 1997.</p> <p>Public Sector Ethics Act 1994.</p> <p><u>Corporate Governance Policy and Guidelines</u></p> <p>General Trust Fund Policy.</p> <p>Information Privacy for Queensland Health Staff: http://QueenslandHealtheps.health.qld.gov.au/privacy/docs/Info_Privacy_Queensland_Health_staff.pdf.</p> <p>Information Standard 42A: Information Privacy Guidelines.</p> <p>Information Standard No 42A: Information Privacy for the Queensland Department of Health.</p> <p>Intellectual Property Fact Sheet No. 1 August 2006.</p> <p>IRM 3.8-3 December 2005 indemnity for Employees and Other Persons (Excluding Medical Practitioners).</p> <p>IRM 3.8-4 January 2003 Indemnity for Queensland Health and other Approved Medical Practitioners.</p> <p>Part 7 Confidential Guidelines: http://QueenslandHealtheps.health.qld.gov.au/privacy/docs/Confidentiality_Guidelines.pdf</p> <p>Queensland Health Researcher User Guide 2008.</p> <p>Queensland Health Guidance in Using the Standard Site Specific Assessment Form 2008.</p> <p>Respecting you Privacy: What Happens to Your Personnel information. http://QueenslandHealtheps.health.qld.gov.au/privacy/docs/Respecting_Your_Privacy.pdf</p>

8. Financial Management of Research:

- This section of the policy applies to the Management of all funds received by Queensland Health, or Queensland Health staff, in relation to research, irrespective of whether identified as a fee-for-service, funded research (e.g. NHMRC, ARC, Queensland Cancer Fund, research for higher degrees) or as a donation or bequest. Management of all research project funds and revenue within Queensland Health must be compliant with this policy and Queensland public sector policy and legislation.
- To comply, revenue in relation to research projects (e.g. sponsored trials NHMRC, ARC, Queensland Cancer Fund, research for higher degrees), which is of a 'fee-for-service' nature, must be managed via District operating funds and not General Trust Funds (GTFs). However, funding received as bequests and donations must remain in, and be administered via, General Trust Funds.
- Funding received for all new research projects that are of a 'fee for service nature' will need to be managed via District operating funds from the outset.
- District Finance Units (DFUs) will need to undertake the steps below to ensure compliance, however, it is the individual researcher's responsibility to ensure that all incoming research funds for their projects (excluding those from bequests / donations) are identified appropriately and placed into quarantined research cost centres within the District operating funds.
 1. Determine the nature / source of the research project fund.
 2. All research project funds acquired through donations and bequests must continue to be administered through cost centres within the General Trust Fund.
 3. DFUs should liaise with the researcher to determine the number of cost centres required (i.e. should several research projects be managed through one cost centre with internal order numbers to identify each project, or should each research project be allocated one cost centre). The availability of these options will be District dependent, however, for larger projects it is preferable to use a cost centre.
 4. For 'fee-for-service' research funds, DFUs should forward a request to Budget Team, Finance Unit to establish a cost centre in research specific District operating funds for each research project/s (i.e. excluding those funds identified in step 2).
 5. Research project revenue must be credited to one of the following account codes (forming part of Category A revenue)
 - 450020 Research Projects — Commercial Organisations (e.g. drug companies) or
 - 450025 Research Projects — Non-Commercial Organisations and / or Charitable (e.g. NHMRC, Heart Foundation)
- All revenues raised must be billed via DFU using an official Queensland Health invoice. Under no circumstances are researchers to bill or raise invoices directly.
- Reimbursement of costs to QH for study related costs are to be promptly reimbursed from the Queensland Health project cost centre.

9. Site Specific Assessment (SSA):

- It is necessary for all researchers to complete a Site Specific Assessment (SSA) in addition to the application submitted to the HREC for each project. Only the District has

responsibility for considering matters of research governance (not the HREC). Access to the SSA is through the Queensland Health On-line portal.

- The Site Specific Assessment Form is to be completed before authorisation for the conduct of research by the District CEO. The SSA must detail the actual monetary and / or in kind cost of the research project being conducted at a Queensland Health site or facility.
- To commence a research project at any Queensland Health site, the investigator must have received written authorisation from the District Chief Executive Officer or their delegate. Authorisation to commence the research project will only be granted when
 - the HREC has granted ethics approval for the protocol; and
 - a SSA has been completed.
- The District Chief Executive Officer and their delegates retain the right to not authorise the commencement of research projects within the District, even if the HREC has granted ethical approval.

10. Review Fees:

- Fee for HREC Review and Site Specific Assessment apply for all Commercially Sponsored Research as presented in Table 1. These fees will be reviewed annually.

Table 1: Schedule of Fees for HREC Review and SSA

Fee	Value
HREC fees for application for research project with full industry sponsorship	\$3300
HREC fees for amendments to research projects with full industry sponsorship*	\$550
HREC fees for addition of sub-studies to research projects with full industry sponsorship #	\$1665
SSA Fee	\$3,300 per site
Independent Scientific and Ethics Review Fee	Cost recovery only

*Amendments include changes to the protocol excluding minor administrative changes

#Sub-studies will be reviewed and fees determined on a case-by-case basis. The HREC may request that the sub-study be submitted as a new application and charge the full fee.

11. Contract Management:

- All research involving Queensland Health staff, premises, resources or patients must be the subject of a written research contract. To improve the efficiency of the contract negotiation process, external parties (e.g. Sponsors, CROs or collaborating organisations) should be provided with a copy of this section of the Policy prior to commencing contract negotiations.
- Within Queensland Health, the delegation to and the authority for signing of contracts on behalf of the State is the Director General (*Acts Interpretation Act 1954*). This authority has been sub-delegated to various officers within Queensland Health through the Queensland Health Contract Signing Delegations 2007.
- All research contracts must be approved and signed by appropriately authorised Queensland Health officers in accordance with the Guide to Contract Signing Delegations 2007. This should take place following legal review of the final document

and on recommendation from the relevant Research Governance Officer that the research proposal be authorised to commence.

- Queensland Health officers involved in contract negotiations should make other parties aware that they are not authorised to bind the State, and that no contract will be formed until a final written agreement has been signed by the appropriate Queensland Health contract signing delegate.
- A research contract is a legally enforceable agreement between two or more parties. It should contain all of the terms on which the parties have agreed to conduct the research project. It is extremely important that these contractual terms are appropriate and acceptable to Queensland Health and consistent with Queensland Health's medical research and development objectives, as the conduct of research may otherwise expose Queensland Health to significant legal liability and risk.
- Ultimately, the contract signing delegate must be satisfied with the proposed contract / transaction before they sign.

12. Key Principles and Clauses for all Research Contracts:

All research contracts should generally include clauses that deal with the following issues.

- Parties – The contract must properly identify and define the parties to the contract. A contract may involve two or more parties. External parties must include their full legal name (including ACN if a company) and registered address. It is recommended that objective evidence be obtained to confirm the type of legal entity with whom Queensland Health is contracting and their full details (for example, a company search). Queensland Health must always be described as “The State of Queensland acting through Queensland Health (insert name of District or Unit)”.
- Term – The contract should state a commencement date and the timeframe within which the research project must be completed. The term of a research contract should generally be for a fixed period and will not involve automatic renewals or extensions, however, the contract may provide mechanisms for the parties to agree to extend the terms. Some contracts may also include conditions precedent, which are actions or requirements that must be met prior to the contract becoming effective (for example, obtaining HREC approval).
- Consideration – This is the exchange of promises by the parties to a contract. In a research contract, this will usually involve the promises by each party to fulfil their respective obligations and roles to conduct the research project. It may also involve payments from one party to another, or the resources (cash or in-kind) that each party is contributing to the project. In relation to each particular research project Queensland Health should carefully assess whether the consideration it is receiving is sufficient and reasonable to cover all of its expected costs and responsibilities in performing the project.
- Payments, GST and Invoicing – Details should be included in the contract regarding the timing and method of any payments to or by Queensland Health. This may include identification of bank account details for EFT payments, whether a party may issue recipient-created tax invoices, and details for payment by cheque. Generally GST will apply to payments unless the other party is foreign, so an appropriate GST clause should be included.

- Obligations, roles and responsibilities of each party – The contract should set out, with as much detail as possible, the roles and responsibilities of each party in relation to the conduct of the research project. This will often be included in a study protocol or funding application document, which can be annexed to the contract as a schedule. Importantly, the contract should oblige all parties to comply with all applicable Australian laws and regulations, as well as national guidelines and standards regarding research. The contract must include clauses regarding the parties' responsibilities for reporting and management of adverse events. The contract should detail the parties' responsibilities regarding records management, completion of case forms or reports and retention and access requirements to study related materials.
- Indemnities – An indemnity is 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 should indemnify Queensland Health against claims by patients arising from the study in terms consistent with the Medicines Australia Standard Forms of Indemnity. In research projects that are investigator-initiated, collaborative or involve funding from non-profit organisations it may be more appropriate for the indemnity clauses to be mutual or specifically tailored to the risks and liabilities that are likely to arise in the context of the project. A contractual indemnity is very different to the issue of indemnification of Queensland Health employees under IRM policies 3.8-3 and 3.8-4.
- Insurance – The contract should include a clause requiring any party who is providing an indemnity under the contract to have and maintain appropriate insurance to meet the anticipated cost of that indemnity if it is relied upon. The amount of insurance required will depend on the types of risks involved with the research project, the likelihood of those risks occurring and the cost/loss that would be incurred if the risk occurs. While this should be considered on a case-by-case basis, it is generally recommended that \$10 million per occurrence for professional indemnity, products liability and public liability insurance is required of commercial sponsors. Other issues to consider in relation to insurance include the difference between policy limits on a per claim basis as opposed to an aggregate basis, and the usual requirement that 'run-off' cover be maintained for a specified period following termination or expiry of the research contract. Any contractual requirement for Queensland Health to have insurance should be legally reviewed to ensure that it appropriately reflects Queensland Health's policies of insurance with the Queensland Government Insurance Fund (QGIF).
- Intellectual Property (IP) – Research conducted in Queensland Health is bound by the Queensland Health IP Policy and Queensland Health IP Principles, as well as the Queensland Government IP Guidelines published by the Department of Tourism, Regional Development and Industry. Research contracts should state the arrangements for use of existing intellectual property and the parties' rights in relation to ownership and use of all new intellectual property developed through the research project. Generally, contracts should clarify that patient medical records (and intellectual property in those records) remain the property of Queensland Health.
- Confidentiality and Privacy – Research contracts should include clauses that require the parties to maintain the confidentiality of any 'confidential information' that they have access to in the course of performing the research project. The term 'confidential information' should always be specifically and carefully defined in the contract. The parties may agree upon certain exceptions to the obligation of confidentiality (for example, if the other party consents or disclosure is required by law). Queensland Health should ensure that patient data and clinical records are defined as confidential.

In addition, Queensland Health should generally impose obligations on external parties regarding the use, handling and disclosure of 'personal information' (which should be a defined term) consistent with its privacy obligations under Information Standard 42A.

- Publications – The contract should include provisions regarding the publication rights of the parties. As a general rule, all research results should be published, subject only to short delays in publication to allow for a party to seek protection of valuable intellectual property or to make amendments to remove any confidential information. Generally the parties should be required to obtain the prior written permission of the other party to the use of a party's name in any publications or promotional material.
- Termination – The contract should expressly state the circumstances in which a party may terminate the contract. Queensland Health should ensure that it has a right to terminate if it forms the view at any time that patient safety necessitates the cessation of the research project. Clauses should also be included regarding the consequences of termination (including, for example, obligations to finalise and submit reports, payment of all funds due and owing up until the date of termination and arrangements for ongoing medical care of the patients).
- Governing law – Queensland Health should ensure that all research contracts are governed by the law of Queensland and that any disputes will be dealt with by Queensland Courts.
- Boilerplate clauses – This refers to clauses that are commonly contained in all contracts (such as no assignment, no waiver, entire agreement, force majeure, no relationship, severance, dispute resolution, notices).
- Most, if not all, of the above issues can be dealt with in a variety of ways through contractual clauses. Many of these issues are often subject to commercial negotiation and compromise to achieve a balanced and reasonable position from each party's perspective. The decision of the District and relevant Queensland Health contract signing delegate to proceed with a research contract should always be made in a fully informed manner following legal advice where necessary to ensure the terms of a contract are appropriate and acceptable and sufficiently protect Queensland Health interests.

13. Template Research Contracts

- The type of research contract required and the nature of the clauses to be included in the contract are influenced by the type of research activity being undertaken. To facilitate contract negotiations and allow for efficient contract formation Queensland Health has developed / adopted a number of template research contracts for use in circumstances involving common types of research activity. The types of research activity that commonly occur within Queensland Health can be broadly categorised into the following three areas:
 - Industry sponsored clinical drug / device trials
 - Contract Research Organisation (CRO) sponsored trials
 - Collaborative/Cooperative trials

14. Industry Sponsored Clinical drug / device studies:

- Industry-sponsored clinical drug / device trials ordinarily include a pharmaceutical or biomedical company as the sponsor, paying Queensland Health to gather information

on a certain drug or device at a Queensland Health facility. The study may involve Queensland Health patients or patients recruited by Queensland Health clinicians.

- Queensland Health has adopted the Medicines Australia Standard Clinical Trial Agreement (MA CTA) as mandatory for all industry-sponsored clinical studies in Queensland Health facilities and contains clauses that are reasonable and acceptable to Queensland Health. The MA CTA is available on the Medicines Australia website.
- MA CTA should be used for all industry-sponsored clinical studies. This does not include clinical trials
 - sponsored by a pharmaceutical or biomedical company but conducted through a clinical research organisation; or
 - sponsored or funded by non-profit organisations, collaborating organisations or that are investigator-initiated.
- The MA CTA requires the sponsor to indemnify Queensland Health against claims by patients involved in the trial in accordance with the Medicines Australia Standard Forms of Indemnity. The Indemnity Form needs to be inserted at Schedule 3 of the MA CTA and Queensland Health officers should ensure that the Indemnity Form is signed by both the sponsor and Queensland Health at the time of signing the research contract. The Indemnity Forms are available on the Medicines Australia website.
- To use the MA CTA a District will need to complete all of the relevant operational details for a particular research project (including the names of the parties, study name and protocol on the front cover of the MA CTA, and all details required in the schedules including payment arrangements and insurance requirements).
- Queensland has agreed with a number of the major pharmaceutical companies for a standard set of clauses to be included as Special Conditions in Schedule 7 in each MA CTA between Queensland Health and that particular company.
- Where a sponsor uses the MA CTA without amendment the District should accept the agreement without further review (subject only to ensuring that the front cover and schedules have been properly completed). If, however, a particular research project is considered high-risk, novel or unusually experimental, it would be prudent for the District to obtain legal advice even if the standard MA CTA is being used.
- Where a sponsor requests amendments to the standard MA CTA, or seeks to use its own research contract, the District should
 - Contact its District or Area Lawyer or the Research Ethics and Governance Unit to check if that company has a standard set of approved Schedule 7 Special Conditions;
 - If so, and the amendments are in accordance with the approved Schedule 7 Special Conditions, accept those changes;
 - If not, seek legal advice on the amendments or the sponsor's contract. This advice (if it involves briefing one of the Queensland Health panel firms) should be at the expense of the sponsor.
- Where legal advice is to be obtained in the circumstances described above, the sponsor should first be advised of Queensland Health's policy on this issue and given the opportunity to use the MA CTA.
- If the sponsor still wishes to use their own contract, or have amendments made to the MA CTA, a written undertaking should be obtained from the sponsor to pay for any legal fees incurred by Queensland Health for review of the non-standard contract.

15. Contract Research Organisation (CRO):

- This ordinarily involves an industry sponsored clinical study of a drug or device where the sponsor is a foreign company and has therefore engaged an Australian CRO to be the contracting entity with Australian institutions. The study may involve Queensland Health patients or patients recruited by Queensland Health clinicians.
- Queensland Health has adopted the Medicines Australia Standard for Contract Research Organisation (CRO) Clinical Trial Agreement as mandatory for all CRO clinical studies in Queensland Health facilities. It contains clauses that are reasonable and acceptable to Queensland Health. The MA CTA is available on the Medicines Australia website.
- Where a CRO uses the Medicines Australia Standard CRO CTA without amendment, the District should accept the agreement without further review (subject only to ensuring that the schedules have been properly completed).
- Where a CRO requests amendments to the standard CRO CTA, or seeks to use its own research contract, the District must obtain legal advice.

16. Collaborative/Cooperative Research:

- Collaborative research includes a wide variety of other research activity that cannot be neatly categorised into one of the above. This category includes
 - Collaborative research projects with non-profit organisations (such as non-government organisations, universities, CSIRO);
 - Collaborative research projects involving funding from State or Commonwealth Departments, the NHMRC, the Australian Research Council or like bodies; and
 - Investigator-initiated trials and research.
- These research projects may or may not involve a clinical trial component, and can involve activities such as
 - clinical drug trial;
 - observation of procedures;
 - use of non-invasive medical monitoring devices on patients;
 - data gathering and analysis;
 - literature reviews;
 - development of training / curriculum documents; and
 - interviews with clinicians.
- Queensland Health has adopted the Medicines Australia Standard for Collaborative and Cooperative Clinical Trial Agreement as mandatory for all Collaborative and Cooperative clinical studies in Queensland Health facilities. It contains clauses that are reasonable and acceptable to Queensland Health. The MA CTA is available on the Medicines Australia website.

17. Non Standard Study Agreement:

- Some project may prescribe the use of the certain contracts (for example, ARC linkage projects will always involve a funding agreement between the Commonwealth and the lead organisation, supplemented by a multi-party linkage collaborative research contract with all of the partner organisations).

- Research projects in this category will require a research contract to be specifically tailored to reflect the particular arrangements for the project, with clauses specifically drafted to appropriately deal with significant issues.
- The requirements for the contract will be affected, for example, if there are complex arrangements regarding pre-existing intellectual property being made available by a party, or for the ownership and use rights (including with respect to protecting or commercialising) new intellectual property, or if one of the researchers is a joint-appointee of the parties to the contract.
- Legal advice should always be obtained on the terms of any research contract for a research project that falls within this category.

18. Obtaining legal advice:

- It is the responsibility of Queensland Health legal officers involved in research projects to ensure that research contracts are legally reviewed (where required in accordance with this policy) prior to signing.
- The contract signing delegate should be provided with a copy of all legal advice in relation to the contract prior to signing.
- A Queensland Health Officer can access legal advice from the following sources:
 1. If you are part of a District, you should seek advice from the District Lawyer or Area Health Services Lawyer relevant to your District;
 2. If your District does not have a District Lawyer, you should seek advice from one of the Queensland Health approved private panel law firms (including a particular firm or practitioner if notified by the Corporate Office Legal Unit);
 3. If you are not part of a District, you should seek advice from the Corporate Office Legal Unit, by submitting a Request for Legal Advice Form (available on <http://Queensland Health/qh.health.qld.gov.au/ibm/css/lalu/advice.htm>) to the LALU email account.

19. Authorship:

- An individual should meet all of the three following conditions to be included in the authorship manuscript list:
 - Substantial contributions to conception and design, or acquisition of data, or analysis and interpretation of data;
 - Drafting the article or revising it critically for important intellectual content; and
 - Final approval of the version to be published.
- A person who does not fulfil these criteria should not be included as an author of a publication. Acquisition of funding, acquisition of data, or general supervision of the research group, alone, does not justify authorship.
- Authorship should be decided early in the planning process of a research project, specifically who will be credited as authors, contributors and who will be acknowledged. This should be reviewed and documented whenever there are changes in participation. A written acknowledgement of authorship should be placed on file in the department of the responsible author.

20. Publication:

- Before proceeding to publication of any research findings, consider whether there are issues of Intellectual Property that should be addressed before findings are presented into the public domain. Contact the QH Intellectual Property Officer for assistance and advice.
- All those involved in research 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.
- Sponsors are under an obligation to support communication of research findings to the wider public. Researchers have a responsibility to their colleagues and the wider community to disseminate a full account of their research as broadly as possible. The account should be complete, and, where applicable, include negative findings and results contrary to their hypotheses.
- A clear agreement between all parties, describing the method of disseminating results, should be reached and documented at the planning stage of any research. This should be incorporated into the research protocol and any relevant clinical trial agreements (CTA) between the researcher and the sponsor.
- A manuscript must include information on all sources of financial and in-kind support for the research and any potential conflicts of interest.
- Researchers must acknowledge the host institution and funding sources of the research. A manuscript should include a statement that the research has not been subject to result-dependent funding or veto of publication by a sponsor and / or government.
- Agreements should protect intellectual property rights of the institution, the researcher, research trainees and sponsors of the research, as appropriate.
- Institutions must ensure that the sponsors of research understand the importance of publication in research and do not delay publication beyond the time needed to protect intellectual property and other relevant interests. The maximum delay in publication should be stated in the protocol and CTA.
- Government sponsors should have a right to review the manuscript for a defined period of time before publication to allow strategies and / or policies to be developed in response to the research findings. The maximum delay in publication should be stated in the protocol and CTA.
- Institutions must ensure that researchers are aware of contractual arrangements that may delay publication.
- Manuscripts should include a statement stating that the project has undergone ethical review prior to commencement of the project (or was exempt from full ethical review). Research projects should not be approved by an HREC retrospectively.

21. Fee for Service Research by Queensland Health Clinical and Statewide Services (CaSS):

- CaSS may provide research services to both the private sector and other government agencies on a fee for service basis.
- The types of research services provided by CaSS includes forensic (biology, chemistry, toxicology, virology) and pathology services. Queensland Health has developed a template Services Agreement and MOU for use for 'fee-for-service' research performed by CaSS.
- For further information please see the CaSS User Guides for those template contracts.
- Some activities of CaSS would fall within the next category of research activities (namely, collaborative research projects with other organisations – please refer to Section 15).
- CaSS operates on a 'fee-for-service' basis. Contact the Research Office for fee details.

