Research Management Policy -
Implementation Standard for Research Governance

1. Purpose
This Implementation Standard identifies the minimum (and auditable requirements) that evidence the implementation of the Research Management Policy for meeting research governance responsibilities which include financial management, contract management and intellectual property.

2. Scope
This standard applies to all Queensland Health 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 patients and staff.

3. Definition of Terms
Definition of all key terms used in this Standard are listed in the Glossary of Policy Terms (Attachment to Research Management Policy).

4. Supporting Documents
- Research Management Policy
- Research Management Policy Implementation Standard - Consent, access, use of confidential health information / data for the purposes of research
- Research Management Policy Implementation Standard - Ethical and Scientific Review
- Research Management Policy Implementation Standard - Conflicts of Interest in Research
- Research Management Policy Implementation Standard – External research funding and infrastructure support
- Queensland Health Clinical Study Agreement Guidance and Advice
Queensland Health Standard: Research Governance

5. Requirements

5.1 Financial Management of Research

- This section of the standard 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 shall be compliant with this policy and Queensland public sector policy and legislation.

- To comply, revenue in relation to research projects (e.g. sponsored trials ARC, Queensland Cancer Fund, research for higher degrees), which is of a ‘fee-for-service’ nature, shall be managed via District operating funds and not General Trust Funds (GTFs). However, funding received as bequests and donations shall remain in, and be administered via, General Trust Funds.

- District Finance Units (DFUs) will 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.

- Study budgets should automatically be adjusted for CPI on the anniversary of the date of the contracts’ signing.

- Regular cost centre reviews must be carried out by Districts to ensure that research cost centres are properly set up with the correct fund code.

- As part of the reporting process the Districts and Divisions are to report on research funds in financial statements.

5.2 Account Management

Determine the nature / source of the research project fund.

- All research project funds acquired through donations and bequests shall continue to be administered through cost centres within the General Trust Fund.

- 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. For larger projects a cost centre should be used.

- 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).
- Research project revenue shall 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. Heart Foundation)
- All revenues raised shall 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 as agreed by the researcher and relevant supporting departments.

### 5.3 Site Specific Assessment (SSA)

- All researchers shall 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).
- The Site Specific Assessment Form shall be completed before authorisation for the conduct of research by the District CEO. The SSA shall detail the actual monetary and / or in kind cost of the research project being conducted at a Queensland Health site or facility.
- Written authorisation of the District Chief Executive Officer, or their delegate, shall be received prior to the commencement of a research project at any Queensland Health site. 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.

### 5.4 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>
<thead>
<tr>
<th>Table 1: Schedule of Fees for HREC Review and SSA</th>
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<tbody>
<tr>
<td><strong>Fee</strong></td>
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<tr>
<td>HREC fees for application for research project with full industry sponsorship</td>
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<tr>
<td>HREC fees for amendments to research projects with full industry sponsorship*</td>
</tr>
<tr>
<td>HREC fees for addition of sub-studies to research projects with full industry sponsorship #</td>
</tr>
</tbody>
</table>
5.5 Contract Management:

- All research involving Queensland Health staff, premises, resources or patients shall 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 Research Management 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 delegated to various officers within Queensland Health.

- All research contracts shall be approved and signed by appropriately authorised Queensland Health officers in accordance with the Queensland Health Contract Signing Delegations 2010 which can be viewed on the Queensland health intranet site: http://qheps.health.qld.gov.au/pl/corp_governance/delegations/contract_sign_deleg.xls

- Contract signing shall take place following legal review of the final document, unless the document is a standard QH approved 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 shall 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. Contractual terms shall be 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.

- The contract signing delegate shall be satisfied with the proposed contract / transaction before they sign.

5.6 Key Principles and Clauses for all Research Contracts

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

- Parties – The contract shall properly identify and define the parties to the contract. External parties shall include their full legal name (including ACN if a company) and registered address. Queensland Health shall 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 shall be completed.

- Consideration – 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. 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. 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 shall include clauses regarding the parties’ responsibilities for reporting and management of adverse events. The contract should detail the parties’ responsibilities regarding records management, provision of equipment or study products, completion of case forms or reports and retention and access requirements to study related materials.

- **Indemnities** – 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.

- **Insurance** – The contract should include a clause requiring any party who is providing an indemnity under the contract to have and maintain appropriate insurance.

- **Intellectual Property (IP)** – Research conducted in Queensland Health should comply with the Queensland Health IP Policy and Queensland Health IP Principles, as well as the Queensland Government IP Guidelines published by the Department of Employment, Economic Development and Innovation. 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.

- **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. Queensland Health should ensure that patient data and clinical records are defined as confidential. Through the research contract, Queensland Health should 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 the Information Privacy Act 2009 (Qld) and the research provisions of the Public Health Act 2005.

- **Publications** – The contract should include provisions regarding the publication rights of the parties. 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. 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.

### 5.7 Template Research Contracts

The type of research contract required and the nature of the clauses to be included in the contract will be determined by the type of research activity being undertaken. Queensland Health has endorsed/adopted a number of template research contracts for use in circumstances involving common types of research activity.
5.8 Industry Sponsored Clinical drug trials

- Queensland Health has endorsed the Medicines Australia Standard Clinical Trial Research Agreement (MA CTRA) 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 CTRA 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 CRO;
  - clinical trials involving collaborating organisations such as Universities; or
  - research projects with non-commercial entities (such as ARC or NHMRC) which are not in the nature of clinical trials or research projects which are investigator-initiated.
- The MA CTRA 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.
- To use the MA CTRA 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).

5.9 Schedule 7 Clauses

- Queensland Health 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 CTRA between Queensland Health and that particular company.
- All Schedule 7 clauses are to be reviewed and approved through the Queensland Health Research Ethics and Governance Unit prior to implementation in a Queensland Health contract.
- Where a sponsor uses the MA CTRA without amendment (apart from inclusion of pre-approved Schedule 7 clauses) 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, the District should obtain legal advice even if the standard MA CTRA is being used.
- Where a sponsor requests amendments to the endorsed standard CTRA, or seeks to use its own research contract, the District should
  - Contact its District 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 external legal fees) 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 standard MA CTRA.
- If the sponsor still wishes to use their own contract or include unapproved schedule 7 clauses, or have amendments made to the CTRA, a written undertaking should be obtained
from the sponsor that they will pay for any legal fees incurred by Queensland Health for review of the non-standard contract.

- Non-approved Schedule 7 clauses intended for general use for all research projects should be submitted to Queensland Health Research Ethics and Governance Unit (regu@health.qld.gov.au) to enable legal review and pre-approval. A fee will be levied for this service.
- “Project Specific” amendments to approved schedule 7 clauses will be submitted by study sites to the District Solicitor for review. A fee will be charged for this service. Project specific amendments to Schedule 7 clauses are approved only for that study and do not affect current approved schedule 7 clauses for that company.
- In the case of “one off, study specific” schedules, the lead site in multi-centre research will conduct the legal review for all QH sites.
- Where amendments are made to previously approved Schedule 7 clauses for general use, those amendments shall be sent for legal review through the Queensland Health Research Ethics and Governance Unit. A fee will be charged for this service.

5.10 Contract Research Organisation (CRO) Clinical Trials

- Queensland Health has endorsed the Medicines Australia Clinical Trial Agreement for Contract Research Organisation (MA CTA CRO) 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 CRO is available on the Medicines Australia website.
- Where a CRO uses the MA CTA CRO 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 MA CRO CTA, or seeks to use its own research contract, the District shall obtain legal advice.

5.11 Collaborative/Cooperative Clinical Trials

- Queensland Health has endorsed a standard agreement for Collaborative or Cooperative Research Group Clinical Trial Agreement (CTA CRG).
- This is mandatory for all CRG clinical trials in Queensland Health facilities.
- The standard contains clauses that are generally reasonable and acceptable to QH, however, this document provides for a very different risk profile in the conduct of a clinical study for QH as compared to the Collaborative CTA, and the MA CTA CRO, in that the other party does not indemnify QH for patient claims in accordance with the MA Standard Forms of Indemnity. As such, Districts should obtain legal advice about the appropriateness of using this document.

5.12 Medical Technology Association of Australia Standard Clinical Investigation Research Agreement

- Queensland Health has endorsed the Medical Technology Association Standard Clinical Investigation Research Agreement (MTAA CIRA) as mandatory for all device clinical studies in Queensland Health facilities. It contains clauses that are reasonable and acceptable to Queensland Health. The MTAA CIRA is available on the Medicines Australia website.
- The MTAA CIRA should be used for all industry-sponsored device clinical studies. This does not include:
  - clinical device trials sponsored by a pharmaceutical or biomedical company but conducted through a CRO;
  - clinical device trials involving collaborating organisations such as Universities; or
- research projects with non-commercial entities (such as ARC or NHMRC) which are not in the nature of clinical trials or research projects which are investigator-initiated.

- The MTAA CIRA 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 MTAA CIRA 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.

- To use the MTAA CIRA 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 MTAA CIRA, and all details required in the schedules including payment arrangements and insurance requirements).

### 5.13 Non Standard Research Agreement

- QH does not have a policy requirement to use any particular template or form of research contract for other research studies not described above. The District legal advisor should provide advice on what agreement is to be used.

- 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.

### 5.14 Obtaining Legal Advice

- It is the responsibility of Queensland Health 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 relevant to your District or from the Corporate Office Legal Unit
  2. If your District does not have a District Lawyer or you are not part of a District, you should seek advice from the Queensland Health Corporate Office Legal Unit.

- The District Lawyer or CO Legal Unit may refer to the matter to a designated external panel law firm where appropriate.

### 5.15 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.

5.16 Publication

Before proceeding to publication of any research findings, issues of Intellectual Property should be addressed before findings are presented into the public domain.

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.

QH 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 (CTRA and CIRA) between the researcher and the sponsor.

A manuscript shall include information on all sources of financial and in-kind support for the research and any potential conflicts of interest.

Researchers shall 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 shall 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 CTRA and CIRA.

Government sponsors should have a right to review the manuscript for a defined period of time before publication to allow strategies and / or polices to be developed in response to the research findings. The maximum delay in publication should be stated in the protocol and CTRA and CIRA.

Institutions shall 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.

5.17 Fee for Service Research by Queensland Health Clinical and Statewide Services (CaSS)

CaSS provides research services to both the private sector and other government agencies on a fee for service basis.

CaSS operates on a ‘fee-for-service’ basis.
6. Review
This Standard is due for review on: 01 July 2011

7. History

<table>
<thead>
<tr>
<th>Date of new / revised policy</th>
<th>Amended to</th>
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<tbody>
<tr>
<td>July 2010</td>
<td>New Implementation Standard: Research Governance</td>
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<tr>
<td>Dec 2010</td>
<td>Version 1.1 – Changes to include new Implementation Standard – External research funding and infrastructure support</td>
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8. Responsibilities

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<tr>
<th>Position</th>
<th>Responsibility (ies)</th>
<th>Accountability/Audit Criteria</th>
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<tbody>
<tr>
<td>Manager, Research Ethics and Governance Unit</td>
<td>This Unit is accountable and responsible for: Undertake annual review of Queensland Health Research Management Policy and (No 24938) and its Implementation Standards in line with national guidelines and relevant legislative requirements.</td>
<td>Research Management Policy and Implementation Standards are reviewed annually and revised if there are policy and process changes. Master registry is maintained (Research Ethics Database – AU RED) of research protocols reviewed and approved to be conducted in Queensland Health</td>
</tr>
<tr>
<td>District CEO</td>
<td>This position is accountable and responsible for: ▪ providing support for the implementation of the Queensland Health Research Management Policy (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.</td>
<td>Annual report of research activity in District. Annual report of research complaints, including research misconduct and fraud. Annual Report on the proportion of protocols approved in less than 60 calendar days. Annual report on the proportion of Site Specific Assessments completed in less than 25 calendar days. Annual report on training attended by District HREC members.</td>
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<tr>
<td>Role</td>
<td>Accountable and Responsible for</td>
<td>Tasks</td>
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| **Research Directors and/or Managers responsible for Research Ethics and Governance** | This position is accountable and responsible for:  
  - providing support and advice to the District Executive, researchers and research sponsor in accordance with the Queensland Health Research Management Policy (No 24938) and its Implementation Standards;  
  - facilitating a culture of safe and high quality research through the promotion and awareness 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.                                      | Prepare annual report of District research activity.  
Prepare research revenue report for the Office of the Chief Scientist.  
Prepare the biannual ABS Research Report.                                                                                                                                                                                                                                      |
| **District Research Governance Officers**                           | This position is accountable and responsible for:  
  - uploading all Site Specific Assessments decisions and maintaining a current record on the AURED;  
  - providing secretariat support for a HREC;  
  - providing administrative support for Site Specific Assessment and authorisation of research; and  
  - Lead and or assist in the preparation on the annual reporting of HREC activity to the NHMRC.                                                                                                               | Accurate data entry into AU RED.                                                                                                                                                                                                                                 |
| **Principal Investigators and Researchers**                         | This position is accountable and responsible for:  
  - conducting research in accordance with national guidelines and the Queensland Health Research Management Policy 2010 (No 24938) and its Implementation Standards;  
  - 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                                                                                                                                                                                                                           | Submit all Site Specific Assessment on QH Online form for uploading into AU-RED.  
Complete a Site Specific Assessment and obtain District authorisation prior to commencement of research.  
Provide scheduled progress and final reports provided to the HREC and Governance Officer as required from authorisation of research.  
Prepare application for access to |
Queensland Health Standard: Research Governance

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<thead>
<tr>
<th>Coordinating Principal Investigators</th>
<th>This position is accountable and responsible for:</th>
<th>Submit all Site Specific Assessment on QH Online form for uploading into AU-RED.</th>
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<tbody>
<tr>
<td>- making records available for review;</td>
<td>- conducting all research in accordance with national guidelines and the Queensland Health Research Management Policy 2010 (No 24938) and its Implementation Standards;</td>
<td>- Complete a Site Specific Assessment and obtain District authorisation prior to commencement of research.</td>
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<tr>
<td>- ensuring compliance with legislative and policy requirements for patient contact, consent and confidentiality of patient information;</td>
<td>- ensuring research practices reflect current professional (ethical and legal) standards for research, including reporting conflicts of interest</td>
<td>- Prepare application for access to confidential health information held by the Department for use in research where required.</td>
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<tr>
<td>- only conducting clinical intervention studies with the essential approved credentialing privileges and experience; and</td>
<td>- responding promptly to reporting and monitoring standards, including adverse events, complaints and clinical incidences for multi-centre research;</td>
<td>- Only conduct research that is consistent with professional privileges and training.</td>
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<tr>
<td>- registering all clinical trials on a publicly accessible clinical trial registry, prior to the commencement of the clinical phase of the trial.</td>
<td>- maintaining good research records available for review;</td>
<td>- Register all clinical trials on the Australian New Zealand Clinical Trials Registry (ANZCTR) or on another authorised clinical trial registry.</td>
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<td></td>
<td>- ensuring compliance with legislative policy requirements for patient contact, consent and confidentiality of patient information;</td>
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<td>- only conducting clinical intervention studies with the essential approved credentialing privileges and experience; and</td>
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<td></td>
<td>- registering all clinical trials on a publicly accessible clinical trial registry, prior to the commencement of the clinical phase of the trial.</td>
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<tr>
<th>Project Liaison Officer/s and Clinical Research Coordinators</th>
<th>This position is accountable and responsible for:</th>
<th>All documentation and records associated with external research partners are maintained and auditable.</th>
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<tr>
<td>- liaising between the Principal Investigator and District Human Research Ethics Committee and Research Governance Office/r;</td>
<td>- 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</td>
<td></td>
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<tr>
<td>- 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</td>
<td>- liaising with the Principal Investigator</td>
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<tr>
<td>- all documentation and records associated with external research partners are maintained and auditable.</td>
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Confidential health information held by the Department for use in research where required.

Only conduct research that is consistent with professional privileges and training.

Register all clinical trials on the Australian New Zealand Clinical Trials Registry (ANZCTR) or on another authorised clinical trial registry.
and research sponsor regarding the management, monitoring and financial reporting of the research project.

<table>
<thead>
<tr>
<th>Research supervisors</th>
<th>This position is accountable and responsible for:</th>
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<td></td>
<td>† liaising between the student and the student liaison officer if the supervisor is not a Qld Health employee;</td>
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<td></td>
<td>† fulfilling a supervisory role and take responsibility for the student and act as a primary source of guidance to the student;</td>
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<td></td>
<td>† ensuring work submitted by research students and trainees is their own and that their data are valid;</td>
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<td></td>
<td>† advising each trainee of applicable government and institutional guidelines for the conduct of research Intellectual Property rights and obligations;</td>
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<td></td>
<td>† ensuring students are familiar with Queensland Health Student Orientation Requirements. (Student Health Professionals’ Clinical Placement or Fieldwork Orientation; and</td>
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<td></td>
<td>† 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.</td>
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All students will have a supervisor. Students will liaise with a student liaison person if the supervisor is not a Queensland Health employee.

Orientation procedures, including signing and submitting the task checklist to the relevant HREC, will be completed.

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Chief Executive Officer, Centre for Healthcare Improvement

Approval Date: 7 September 2011

Implementation Date: 7 September 2011