Health and Medical Research, Preventive Health Unit

Standard Operating Procedures for Queensland Health Research Governance Officers

Version 5 – November 2013

Great state. Great opportunity.

Queensland Government

Acknowledgements

These Standard Operating Procedures (SOPs) have been developed by Health and Medical Research, Preventive Health Unit, Queensland Department of Health with valuable input and contributions from Queensland Hospital and Health System Research Governance Officers (RGOs).

These SOPs are the minimum standard for research governance review of research that has been ethically approved under the National Approach.

Contents

Introduction

Purpose and scope

The Standard Operating Procedures (SOPs) in this document outline Queensland Health's responsibilities for the conduct of research within the Department of Health (DoH) and Hospital and Health Services (HHSs) which are consistent with the following guidance documents:

- National Health and Medical Research Council's (NHMRC) *National Statement on Ethical Conduct in Human Research* (2007) (*The National Statement*);
- NHMRC and Universities Australia *Australian Code for the Responsible Conduct of Research* (2007) (*The Code*);
- NHMRC *Research Governance Handbook: Guidance for the national approach to single ethical* review (December 2011);
- NHMRC *Framework for Monitoring: Guidance for the national approach to single ethical review of multi-centre* research (January 2012);
- Queensland public health system *Research Management Policy* (QHRMP) (29 June 2012);
- Queensland Health Research Ethics and Governance Directive (2013); and
- Therapeutic Goods Administration, *Notes for Guidance on Good Clinical Practice* (CPMP/ICH/135/95) 2000 (TGA GCP).

Each HHS should have appropriate research governance. Research governance is a local institutional due-diligence assessment. It encompasses the assessment of legal, financial, regulatory and contractual issues. These SOPs outline how a Research Governance Officer (RGO) assesses this in practice.

These SOPs apply to the conduct of all human research that uses Queensland Health facilities, patients, staff, tissue and data (medical and personal records or information).

Implementation

These SOPs are here to assist RGOs and ensure a consistent approach for researchers across the state. They are the minimum standard for research ethically approved under the National Approach.

Definitions and Abbreviations

Adverse event (AE)	Any untoward medical occurrence in a research participant using an investigational product which does not necessarily have a causal relationship with the product. Therefore, an adverse event (AE) can be any unfavourable and / or unintended sign (including an abnormal laboratory finding), symptom, or disease temporally associated with the use of a medicinal (investigational) product, whether or not related to the medicinal (investigational) product.
Amendment	A change to the Human Research Ethics Committee (HREC) approved application including the protocol or supporting documentation. If the amendment is administrative in nature an HREC amendment review fee may be waived for commercially sponsored research. Examples of Administrative Amendments include: • correction of typographical errors in any study documentation; • amended contact details for the sponsor or study staff; or • appointment of new support staff.
Applicant	For multi-centre studies the Coordinating Principal Investigator (CPI). For single site studies the Site Principal Investigator (PI).
Associate Investigator (AI)	Another term used for Sub-investigator.
AU RED	Australian Research Ethics Database. A secure web-based research ethics database used by HREC Administrators, Research Governance Officers (RGOs) and other ethics office administrative staff to store ethics and governance documents, applications and correspondence in relation to studies submitted to a Queensland Health Human Research Ethics Committee or Research Governance Officer (RGO).
The Australian Code for the Responsible conduct of Research (*The Code*)	The *Australian Code of for the Responsible Conduct of Research* (2007) (the *Code*). This guides institutions and researchers in responsible research practices and promotes integrity in research. It shows how to manage breaches of the *Code* and allegations of research misconduct, how to manage research data and materials, how to publish and disseminate research findings, including proper attribution of authorship, how to conduct effective peer review and how to manage conflicts of interest. It also explains the responsibilities and rights of researchers if they witness research misconduct.
Central Coordinating Service (CCS)	The Central Coordinating Service (CCS) allocates multi-centre studies to an appropriately Certified HREC for review. This will be displayed on *AU RED* as *Applications Booked in through CAS*. Researchers must complete a booking form to enable the study to be allocated for HREC review. The booking form can be found by following this link: http://www.health.qld.gov.au/ohmr/html/regu/cen_coord_serv.asp All studies being conducted in more than one site must be referred to the CCS.
Certified HREC	An HREC which has had its processes assessed and certified under the National Health and Medical Research Council (NHMRC) National Certification Scheme. NHMRC certification lasts for three years. • To access information on the NHMRC Certification Scheme, click on this link: http://hrep.nhmrc.gov.au/

	• To find a certified HREC, follow this link: http://www.nhmrc.gov.au/_files_nhmrc/file/health_ethics/homer/Certified%20ethical%20review%20process%20v0_11.pdf
Clinical Audit	Quality Assurance programmes may use planned clinical audits along with other monitoring tools to ensure that standards are being met. A Clinical Audit is not research. • Clinical audit tells us whether we are doing what we should be doing and how well we are doing it. Clinical audit is about quality and finding out if best practice is being practised. • Research is about obtaining new knowledge and finding out what treatments are the most effective. Research tells us what we should be doing. Health and Medical Research policy is to make a clear distinction between clinical audit and research and the policy is that clinical audit does not need approval from a research ethics committee. Even if an ethical opinion is sought for a clinical audit and even if an application is made under the Public Health Act to disclose confidential information without consent, clinical audits do not require research authorisation as they are not research activities. Local approval processes apply for quality assurance activities.
Clinical Research Coordinator (CRC)	The person designated by the Principal Investigator (PI) to be responsible for coordinating the conduct of the research project, including scheduling of participant visits, liaison with Sponsor personnel and the HREC / Research Governance Office(r) (RGO). May also be known as the Site Coordinator or Contact Person.
Contact Person	The person designated by the Principal Investigator (PI) to be responsible for liaising with the HREC / Research Governance Office(r) (RGO). May also be known as the Site Coordinator or Clinical Research Coordinator.
Clinical Research Associate (CRA)	A Sponsor or Contract Research Organisation (CRO) representative employed to monitor clinical trials. The CRA ensures compliance with the clinical trial protocol, checks site activities, reviews Case Report Forms (CRFs) and acts as a communication conduit between sites and the sponsor organisation.
Confidential Information	Confidential Information means any information that— (a) is about a person who is receiving or has received a public sector health service; and (b) could identify the person. *Hospital and Health Boards Act (2011)* See also *Personal Information*
Contract Research Organisation (CRO)	An organisation (commercial, academic or other) contracted by the sponsor to perform one or more or a sponsor's trial-related duties or functions.
Coordinating Principal Investigator (CPI)	The Investigator responsible for coordinating a multi-centre research study, and the submission and communication of all subsequent requests and notifications to the site PIs and Reviewing HREC. The CPI and their team are responsible for coordinating the HREC applications and correspondence throughout a multi-centre study, on behalf of the Accepting PIs for which the CPI is responsible. For single site studies the terms Coordinating Principal Investigator, Coordinating Principal Researcher, Site Principal Investigator and Principal Investigator are all synonymous. Guidance documents for undertaking the role of a CPI are on the HMR website:

	http://www.health.qld.gov.au/ohmr/html/Health Research Team/for_researcher.asp
Department of Health (DoH)	The Department of Health manages the health system in Queensland.
DoRA Database of Research Activity.	A Queensland Department of Health website listing all research studies being conducted within Queensland Health. Permission must be obtained from the Sponsor to publish details to the website. The consent to publish in DoRA is a question in the Site Specific Assessment form (SSA).
Good Clinical Practice (GCP)	An international ethical and scientific quality standard for designing, conducting, recording and reporting trials that involve human participants. May also be referred to as the International Conference on Harmonisation Good Clinical Practice (ICH GCP). For further information go to: http://ichgcp.net/
Health and Medical Research (HMR)	Health and Medical Research formally known as the Research Ethics & Governance Unit (REGU) or the Office of Health and Medical Research (OHMR).
Hospital and Health Boards Act 2011	The Act that recognises and gives effect to the principles and objectives of the national health system agreed by Commonwealth, State and Territory governments. The object of the Act is to establish a public sector health system that delivers high quality hospital and other health services in Queensland having regard to the principles and objectives of the national health system. Part 7 of the Act provides the legislation that governs release of Confidential Information. http://www.legislation.qld.gov.au/LEGISLTN/CURRENT/H/HHNA11.pdf
Hospital and Health Service (HHS)	Hospital and Health Services (HHSs) operate and manage a network of public hospitals and health services within a defined geographic or functional area within Queensland.
Human Research Ethics Committee. (HREC)	Human Research Ethics Committees (HRECs) review research proposals that involve humans or their tissue or data. HRECs are established by organisations, which register their HREC with the NHMRC. It may also be referred to as the Reviewing HREC in multi-centre research studies.
HREC Administrator	An employee of the institution who provides administrative support and advice on the institution's processes for ethical review of research studies. The HREC Administrator reports to the Chair of the HREC in matters related to the activities of the Committee. The terms HREC Coordinator and HREC Administrator are interchangeable.
Individually Identifiable Data	Where the identity of a specific individual can reasonably be ascertained. Examples of identifiers include the individual's name, image, date of birth, or address (*National Statement on Ethical Conduct in Human Research*, 2007).
Low and Negligible Risk Research Form (LNR Form)	An application form used for research which is defined as low or negligible risk. The form is available on the *Online Forms* website.
Low Risk Research	Section 2.1.6 of *The National Statement* (2007) describes research as low risk where the only foreseeable risk is one of discomfort. Where the risk, even if unlikely, is more serious than discomfort, the research is not low risk.
Multi-centre Research (MCR)	Includes research conducted through the collaboration of at least two unique institutions that may be situated in more than one state or territory or within a single jurisdiction. It does not refer to research being conducted at several sites or locations

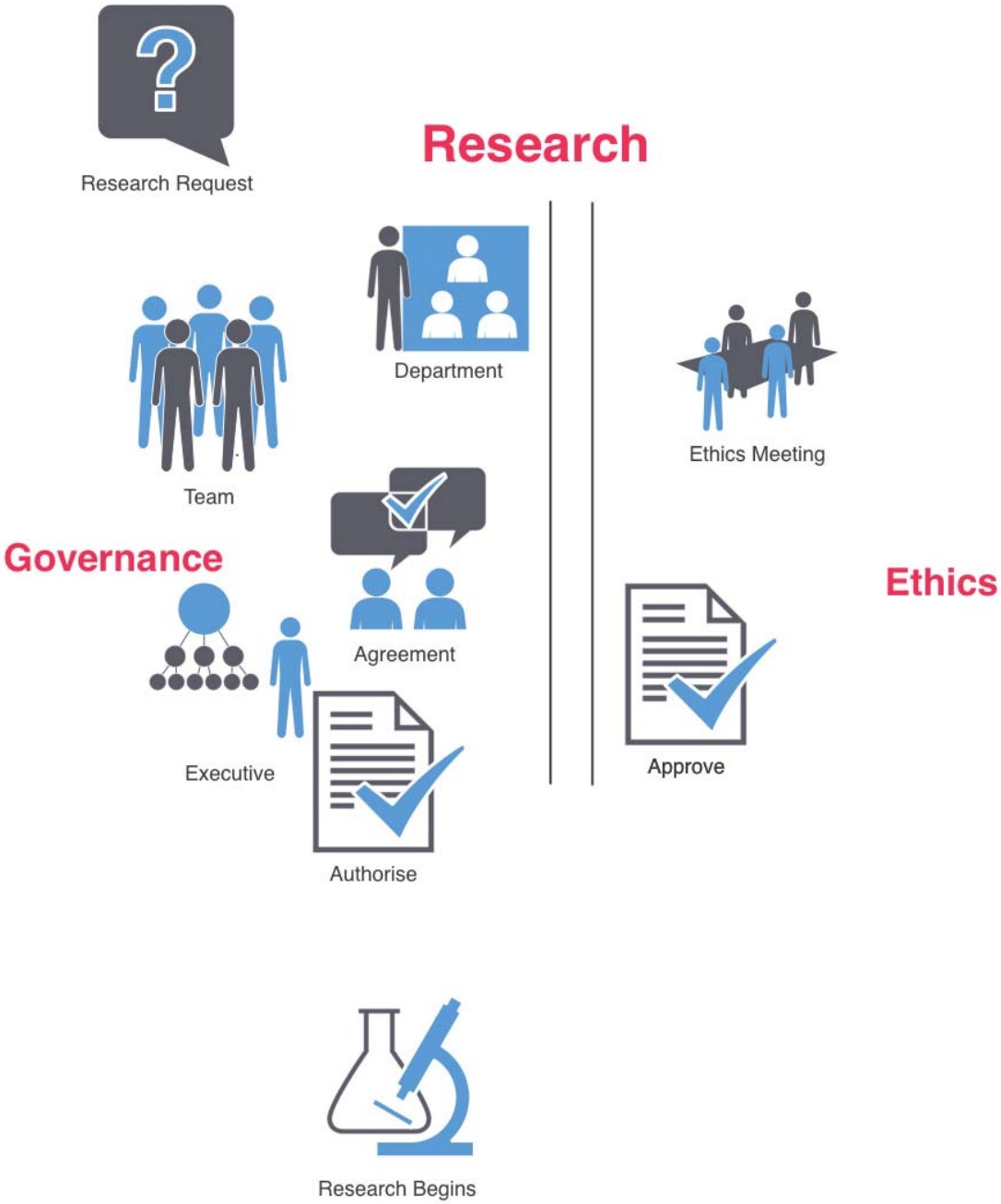
	of a single institution. (Certification Handbook – National Certification Scheme of Institutional Processes related to the Ethical Review of Multi-centre Research, November 2012, p 1) Multi-centre research must be allocated via the CCS for HREC review.
National Mutual Acceptance	The national mechanism to allow specific types of multi-centre research to be reviewed by an NHMRC Certified HREC, and for that HREC review to be accepted across all public health institutions within participating jurisdictions. For further information, go to: http://www.health.qld.gov.au/ohmr/html/regu/mutual_accept.asp
The National Statement (*NS*)	*The National Statement on Ethical Conduct in Human Research* (2007) Revised 2009. A guidance document developed by the NHMRC, the Australian Research Council and the Australian Vice-Chancellors' Committee to provide guidelines for researchers, HRECs and others conducting ethical review of research. It also states institutions' responsibilities for the quality, safety and ethical acceptability of research that they sponsor or permit to be carried out under their auspices. http://www.nhmrc.gov.au/guidelines/publications/e72
NEAF National Ethics Application Form.	There are two formats for this document – the *NHMRC* version, and the *Online Forms* version. Both formats are acceptable for HREC review. The *Online Forms* version is the preferred form for use in Queensland Health HRECs. The *NHMRC* version of the form must be transferred to the *Online Forms* version to enable it to be uploaded to *AU RED*. The Site Specific Assessment form (SSA) is only able to be created out of the *Online Forms* version of the NEAF.
Negligible Risk Research	Section 2.1.7 of The *National Statement* describes research as *negligible risk* where there is no foreseeable risk of harm or discomfort; and any foreseeable risk is not more than inconvenience. Where the risk, even if unlikely, is more than inconvenience, the research is not negligible risk.
Non-Identifiable Data	Data which have never been labelled with individual identifiers or from which identifiers have been permanently removed, and by means of which no specific individual can be identified. A subset of non-identifiable data are those that can be linked with other data so it can be known that they are about the same data subject, although the person's identity remains unknown. (*National Statement on Ethical Conduct in Human Research*, 2007)
Online Forms	The *Online Forms* website is an online system that enables users to complete their applications for research ethics and governance review electronically. The website hosts a licensed copy of the NHMRC's NEAF, as well as the site specific assessment forms for the public health systems of New South Wales, Queensland, South Australia and Victoria. www.ethicsform.org/au/SignIn.aspx
Opt Out Consent process	A consenting process where the default position is that potential participants are in the project, unless they opt out. It is less costly and time consuming and results in greater levels of participation. The risk is that people will participate without understanding or really wanting to participate. It is incumbent upon the researchers and HRECs to ensure that the use of Opt Out consent is ethically defensible and is considered informed consent. There are few instances in medical research involving humans, where this would be an acceptable form of consent. In Queensland, a *Public Health Act 2005* (*PHA*) approval is required to disclose confidential information without the consent of a person

Personal information	Personal information is information or an opinion, including information or an opinion forming part of a database, whether true or not, and whether recorded in a material form or not, about an individual whose identity is apparent, or can reasonably be ascertained, from the information or opinion. *Information Privacy Act 2009* See also *Confidential Information*
Principal Investigator (PI)	The investigator responsible for the overall conduct of the research study at a site. • For multi-centre studies the PI may be known as the Accepting PI if they do not have CPI responsibilities. • For single site studies the terms Coordinating Principal Investigator, Coordinating Principal Researcher, Site Principal Investigator and Principal Investigator are used interchangeably.
Quality Assurance Activity (QA)	A clinical governance activity that is a requirement of the compulsory *National Safety and Quality Health Service Standards* and an associated *Australian Health Service and Quality Accreditation* (AHSSQA) Scheme. http://www.safetyandquality.gov.au/wp-content/uploads/2011/09/NSQHS-Standards-Sept-2012.pdf This includes patient satisfaction surveys, surveillance and monitoring and clinical audits. If there are research elements then it will be reviewed as research activities requiring ethics approval and research authorisation,
Queensland Health	The term used to describe reference to the Department of Health and Hospital and Health Services.
Re-identifiable Data	Data from which identifiers have been removed and replaced by a code, but it remains possible to re-identify a specific individual by, for example, using the code or linking different data sets (*National Statement on Ethical Conduct in Human Research*, 2007)
Research Authorisation	Authorisation issued by the HHS Chief Executive (CE) or delegate to conduct research at a Site within their jurisdiction. Authorisation is contingent upon receiving HREC approval and completion of governance requirements which may include an SSA form. The maximum time given for research authorisation is 25 days from receipt of a valid governance application.
Research Governance Office(r) (RGO)	The Office(r) or coordinated function within an institution / HHS whose responsibilities are: • assessing the site-specific aspects of ethically approved research applications; • making recommendations to the HHS CE or delegate as to whether a research study should be granted authorisation at that site; and • monitoring authorised research at the site to ensure it meets appropriate standards.
Research Governance Process	The process by which an RGO assesses the suitability of study to take place within their institution / HHS and recommends authorisation to the HHS CE. Once authorised, the study may commence at that institution / HHS.
Reviewing HREC	The certified HREC that has been allocated to review research studies.
60-day clock	The period of 60 review days allowed for the deliberation of an ethical decision on an application. For research not requiring review at a full HREC meeting, the clock starts on receipt of a valid application. For research requiring review at a full HREC meeting, the clock starts on the relevant HREC meeting closing date. The 60-day

	time limit excludes stop clock days. May also be called 60 Review Days.
Serious Adverse Event (SAE)	The definition of a Serious Adverse Event (SAE) will be defined by the Sponsor and included in the Protocol. Generally, an SAE in human drug trials is defined as any untoward medical occurrence that at any dose, results in death, is life-threatening, requires inpatient hospitalization or prolongation of existing hospitalization, results in persistent or significant disability/incapacity, is a congenital anomaly/birth defect, or requires intervention to prevent permanent impairment or damage. Suspected Unexpected Serious Adverse Reactions (SUSARs) are considered a subset of SAEs.
Single Ethical Review Process (SERP)	The mechanism to allow ethical review of multi-centre research by one NHMRC Certified HREC rather than submitting a study to multiple HRECs for review.
Single site research	Research to be conducted at one site only.
Site Coordinator	The person designated by the Principal Investigator (PI) to be responsible for liaising with the HREC / RGO. May also be known as the Clinical Research Coordinator, Contact Person or Study Liaison Officer.
Site-Specific Governance Amendment	An amendment request for an authorised research study that may be submitted by the applicant to the RGO only (thereby by-passing the HREC). Examples would be changes to site contracts and changes to participating site staff other than the PI.
Site Specific Assessment Form (SSA)	A tool to assist RGOs in the research governance process to document the level of support and suitability of a research study to be conducted at a site, irrespective of whether that study is multi-centre or single site.
Site Start Date	The site start date refers to either the anticipated first point of recruitment (i.e. the date when the advertising or screening for participants begins) or start of data collection.
State Specific Modules	Victoria, Western Australia and the Australian Capital Territory have developed additional modules for HREC review that must be completed and submitted as part of the HREC review of clinical trials, when sites from those States / Territories are participating in multi centre research. For further information go to: Vic: http://www.health.vic.gov.au/clinicaltrials/application-instructions.htm#vsm WA: http://www.health.wa.gov.au/researchdevelopment/home/hrec.cfm#ethics ACT: http://healthresearch.anu.edu.au/human-research-ethics-committee.html
Stop Clock facility	For HREC applications, the time when the 60-day clock is stopped while awaiting a satisfactory response from the applicant to a written request from the HREC for further information or clarification. The clock will re-start automatically when a response from the applicant is logged in to *AU RED*. For SSA applications, the time when the 25-day clock is stopped while awaiting a satisfactory response from the applicant to a written request from the RGO for further information or clarification.
Study Site	Means the location(s) under the control of the Institution where the study is actually conducted.
Study Start Date	The study start date refers to either the anticipated first point of recruitment (i.e. the date when the advertising or screening for participants begins) or the start of data collection at any site involved in the study.
Sub Investigator	May also be called Associate Investigator (AI) or Associate Researcher. ICH GCP defines a sub-investigator as *any individual member of the clinical trial team*

	designated and supervised by the investigator at a trial site to perform critical trial-related procedures and/or to make important trial related decisions.
25-day clock	The period of 25 days allowed for the SSA authorisation by the HHS CE or delegate of a research application. The clock starts on receipt of a valid governance application.
Therapeutic Goods Administration (TGA)	The Therapeutic Goods Administration is the agency responsible for regulating therapeutic goods. http://www.tga.gov.au/about/about.htm
Validation	An administrative check carried out by an HREC Administrator or RGO to verify that all applicable application documentation is submitted prior to review. Decisions on validation should be made within one week of receipt.
Validation date	• For research not requiring review at a full HREC meeting, the date on which a valid application is received by an HREC Administrator. • For research requiring review at a full HREC meeting, the relevant HREC meeting closing date. • For research governance: the date on which a valid application is received by an RGO.

SECTION 1: Research Governance Review



General Guidance

1.1 The research governance process is separate from the ethical review considered by Human Research Ethics Committees (HRECs) but is an essential review prior to the commencement of a research study.

1.2 Prior to authorisation being granted by the HHS CE or delegate to commence a research project, the RGO undertakes an assessment of the research project based on the information provided in the governance application. This may include the SSA form and other supporting documentation submitted by the Site PI. This assessment considers the following matters:

- the appropriateness of the research project in terms of the research goals of the HHS and whether the institution wishes the research to be conducted at its site, i.e.: does this research fit within the HHS research investment strategy?;
- the resource (financial, human, equipment, infrastructure) implications of the research project for the HHS and whether these resources are considered to be appropriate, accountable and available;
- the expertise and experience of researchers, ensuring that relevant training for researchers is conducted before the research commences at the site;
- the compliance of the research project with relevant laws, policies and codes of conduct relating to matters such as privacy, confidentiality, consent, bio-safety, professional standards, contracts, intellectual property and radiation safety;
- the legal requirements of the research project; and
- co-ordination of on-site monitoring of research projects (related to research conduct, risk levels of research, and serious adverse events (SAEs)) at the recommendation of the Reviewing HREC or in response to local events.

1.3 In conducting the assessment, the RGO may seek advice / endorsement from other relevant personnel as is considered necessary. This may include communication with the Reviewing HREC for further clarification and approval. Collaborative communication is encouraged to streamline processes and to reduce duplication.

1.4 Prior to completion of the HREC review, the Site PI can discuss site-specific arrangements (such as contractual arrangements and budget) with the RGO to assist in the completion of the governance application.

1.5 Heads of Department should be consulted early to assist in the completion of the governance application and expedite the governance review.

1.6 Parallel governance and HREC review is required for commercially sponsored clinical trials and where possible for all other research. A completed governance application may be submitted prior to the final contract however, the RGO, (in consultation with their legally authorised representative, when appropriate) must review the contract schedules and ensure that they are consistent with the application submitted. If there is a difference, additional confirmation from the impacted signatories must be sought. HREC approval should be considered as a part of the due-diligence / governance review.

1.7 The governance application can be submitted prior to an HREC giving an ethical decision for the project. Authorisation to commence the project however, cannot be issued until HREC Approval has been granted.

1.8 The RGO reviews all governance applications to assess and provide advice to the HHS CE or delegate. The RGO provides an outcome recommendation to the HHS CE or delegate, who retains responsibility for authorising the conduct of research at the site / HHS.

Elements of the Governance Application

1.9 The RGO ensures that the appropriately designated personnel have assessed the nature of the research project and its implications for the HHS. The RGO should not reassess or override the

opinion of these people without consultation. The minimum assessment that should take place is as follows:

- Heads of Department approval of:
  - the recruitment process at the site;
  - the human resource impact – that is, how many staff are involved and what is the time commitment of those staff?; and
  - the material resource impact – will the project require the use of computers, interview rooms, treatment rooms or other equipment – how is this to be provided/paid for?
- Business Manager or delegate approval of the financial resource impact – is there any payment to the HHS to conduct the study or is the researcher asking for in-kind support?
- Is a legal opinion required regarding:
  - the contractual impact – is a legally binding contract in place that sets out the responsibilities and obligations of each party involved in the project?;
  - has this contract undergone previous legal review or is it a pre-agreed template?; and
  - intellectual property impact – who owns any intellectual property generated in the course of the project, how is this to be used in the future?
- Insurance and indemnity – what are the insurance and indemnity provisions for the project? What level of insurance cover is being proposed and is it appropriate for the type of study being undertaken?
- Ensuring the relevant authorisations are in place:
  - *Public Health Act 2005* (*PHA*) approval letter;
  - Pathology Queensland;
  - Queensland Civil and Administrative Tribunal (QCAT);
  - Coronial approval;
  - Institutional Biosafety Committee;
  - NHMRC Gene and Related Therapies Research Advisory Panel (GTRAP) or Cellular Therapies Advisory Committee (CTAC);
  - NHMRC Licensing Committee; and
  - Australian Radiation Protection and Nuclear Safety Agency (ARPANSA) code compliance.

Electronic Signatures

1.10 The *Online Forms* SSA form is able to be signed electronically by the PI. If an electronic signature is visible in the SSA form, then the researchers are not additionally required to hand-sign the form. However, scanned copies of a signature that has been cut and pasted into the form are not acceptable unless there is clear evidence of the intent of the person that they support and agree with the information in the document.

The Site Specific Assessment Form

Project Details

1.11 This information enables the RGO to liaise with the Reviewing HREC and register the completed governance application in the Australian Research Ethics Database (*AU RED*). It also identifies whether the study is single site or multi-centre research.

Description of Project in Plain Language

1.12 This section of the SSA form should be detailed enough to enable the RGO to readily ascertain the nature of the research project and its possible implications for the site.

Study Type, NHMRC Group and Fields of Research

1.13 This information is required by the HHS, to enable them to provide an annual report to the Chief Scientist or provide information to the HHS CE, Health and Medical Research or the Minister for Health if requested. This information must be supplied by the researcher.

NHMRC Group and Field of Research

1.14 This information reflects disease and health issues that are relevant to the Queensland research priorities.

Research Personnel

1.15 The RGO requires information relating to the suitability of the Site PI to undertake the study including professional qualifications, knowledge of the research field, expertise in procedures involved, credentialing privileges and previous research experience. Sign off by the Department Head provides some assurances of the above.

1.16 A current Curriculum Vitae (CV) (recommended two-page maximum) must be provided for each researcher at the HHS / site if not submitted in the previous two years. The CV should outline the researcher's clinical and research experience, however in the case of senior experienced researchers, this should be limited to recent research activities considering a two page recommended maximum.

1.17 Credentialing refers to the credentialed scope of clinical practice. There is no requirement for the RGO to receive the credentialing documentation or make an assessment of the scope of practice. The Medical Officer declares that they are credentialed to undertake all tasks required of them by participating in the research project, and that they are operating within their Scope of Practice, or that measures have been taken to address any deficits.

1.18 All associate researchers at the site / HHS should be included in this section, and all medical staff must make the declaration about their current credentials.

Training

1.19 This is a declaration that the Site PI and / or research team has had training or experience in research methods (including informed consent), Good Clinical Practice (GCP) and procedures

specific to the research being undertaken at the site. If there is a knowledge deficit, the PI should outline how this will be rectified, i.e. who is providing the training and when this is going to occur.

Recruitment

1.20 Recruitment methods should be compliant with all relevant privacy policies and legislation at Federal and State level and it should be established whether the identified participant group is appropriate and available at the HHS site. Department Head approval should satisfy the RGO of this requirement.

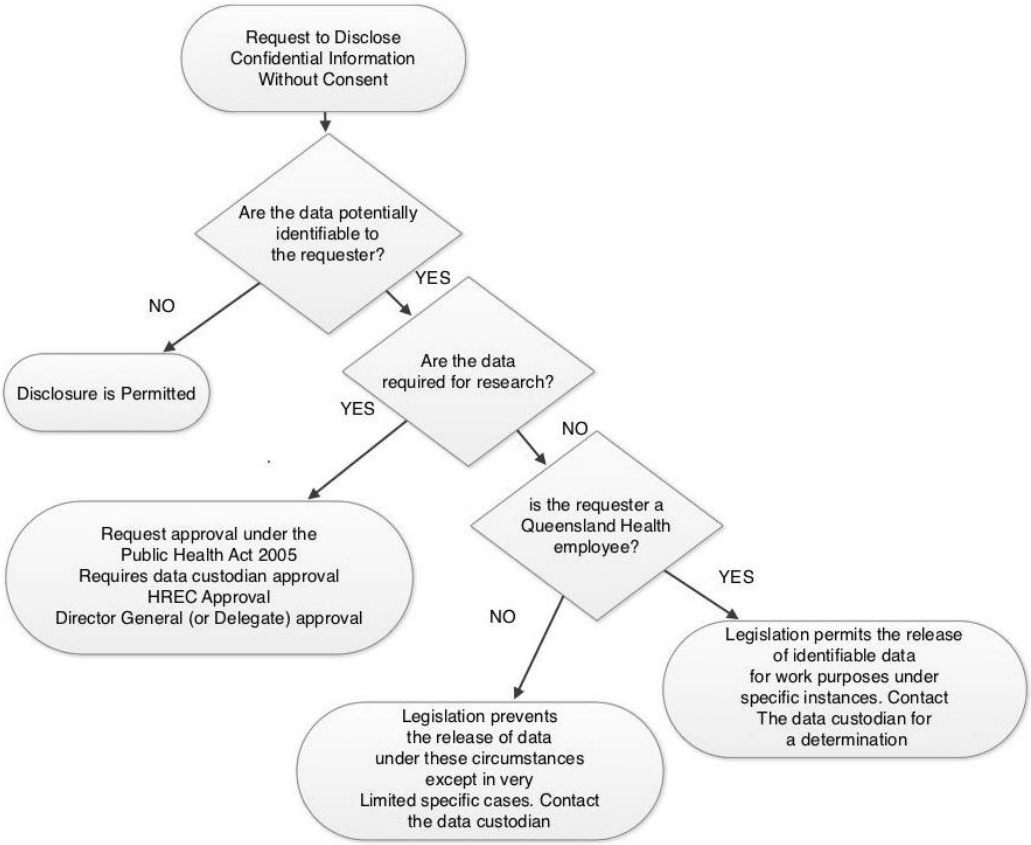
Anticipated Start and Finish Dates for the Research Project

1.21 The provision of this information enables the RGO to consider whether the requested use of facilities, staff and resources will be available and whether it is appropriate to allow the research project to commence at the site, given the expected commencement and duration of the research project and consider if there are other competing studies being undertaken concurrently at the site.

1.22 Research should commence within 12 months of the date of HREC approval. The PI should notify the RGO if the research cannot start within 12 months of the HREC approval date and give a justification for the delay in starting. A copy of the Annual Report provided to the Reviewing HREC is acceptable as means of notification of the status of the project.

1.23 The finish date refers to when no further contact with participants / data source is foreseen including the data analysis and reporting period.

The *Public Health Act 2005* and Studies Requiring Queensland Health staff to disclose confidential information



1.24 The *Hospital and Health Boards Act 2011* (Qld) Part 7 defines Confidential Information and outlines the circumstances under which Confidential Information may be disclosed.

1.25 s144 states that confidential information can be disclosed if the information is related to an adult and they have consented to the disclosure. If the information is related to a child, the parent or guardian must consent and the child must consent if the health professional believes the child is of sufficient age and mental and emotional maturity to understand the nature of consenting to the disclosure. If the child is not capable of consent, then the Health Professional must reasonably believe the disclosure of the information is in the child's best interest.

1.26 s143(1) further states that a designated person *may* disclose Confidential Information if the disclosure is required or permitted by an Act or law.

1.27 The *Public Health Act 2005* (Qld) *('PHA')* is the instrument by which confidential health information may be accessed for the purposes of research - as it is defined in the *PHA*.

1.28 When researchers require access to and use of potentially re-identifiable data and confidential information for the purposes of research, without the consent of the person to whom the information relates, an application must be made under the *PHA,* s281-284 to allow the data custodian to disclose the confidential information without breaching the *Hospital and Health Board Act 2011*.

1.29 The *PHA* s280 describes the types of investigations falling within its definition of research as being:

- a biomedical study (a study of the biological determinants of health and disease that establishes the biological basis for preventing, treating and curing disease) e.g. laboratory based research, genetic research;
- a clinical and applied study (a study of the effectiveness of strategies to diagnose and treat disease or illness) e.g. clinical trials;
- an epidemiological study (a study of the distribution and determinants of health related state or events in particular populations) e.g. cross-sectional study;
- an evaluation and planning study (a study for appraising or measuring the value of a health intervention; or designing and projecting current and future health services) e.g. evaluation of a health promotion program; or
- a monitoring and surveillance study (a study for keeping watch over the health of the population or individuals to control the spread of disease and maintain health and well-being) cohort study.

1.30 Legal advice suggests that doubt exists as to whether a validly appointed substitute decision maker for personal matters, including health care of a person who lacks capacity ('the person'), can consent on behalf of the person to the disclosure of confidential information for purposes such as research, quality assurance, professional development, teaching and training. This conclusion is based on the premise that research, quality assurance, professional development, teaching and training do not neatly fall within the definition of 'health care'.

1.31 A specific statement regarding the consent for disclosure is advised in the substitute consent statement. For the avoidance of any doubt a Queensland Health staff member will not be in breach of the *Hospital and Health Boards Act 2011* if they disclose confidential information without the consent of the person to whom the data relates to where approval has been granted under the *Public Health Act 2005*.

1.32 Legal advice suggests that an *Opt Out* approach to consent cannot be relied upon as consent and a *PHA* application will be required.

1.33 *PHA* application form must be completed and submitted to HMR for consideration and approval, prior to governance authorisation being granted. Go to:
http://www.health.qld.gov.au/ohmr/html/regu/aces_conf_hth_info.asp

1.34 All research projects requesting a waiver of the requirement for consent must be reviewed by an HREC, as per s282(2)(i) of the *PHA.*
http://www.legislation.qld.gov.au/LEGISLTN/CURRENT/P/PubHealA05.pdf

1.35 The decision to grant the waiver of consent must be recorded in the HREC Approval letter.

1.36 Examples of research that may seek consideration for a waiver of the requirement of consent are:

- Accessing potentially identifiable data from data sets – *PHA* required
- Accessing participant records – *PHA* required
- Accessing identifying tissue from tissue banks – *PHA* required.

1.37 The *National Statement* section 3.2.10 states that *researchers should recognise that data stored in an identifiable form cannot be used in research that is exempt from ethical review.*

1.38 The provision of this information enables the RGO to ensure that access to confidential health information held by the Queensland Health, and disclosed to researchers, meets the requirements under s281 of the *PHA*. In addition, it assures the RGO that the researcher has contacted the data custodian to certify that the data is both available and accessible. http://www.legislation.qld.gov.au/LEGISLTN/CURRENT/P/PubHealA05.pdf

1.39 When researchers require Queensland Health staff to disclose confidential information, without consent, for the purposes of research, the provision of the *PHA*, s282 must be considered. This includes, but is not limited to, health information held and owned by Queensland Health from the:

- Health Information Management (Formerly the Medical Records Department);
- Cancer Registry;
- Perinatal Statistics Collection;
- Pap Smear Register;
- Inpatient Data;
- Pathology samples from Clinical and Statewide Services (CaSS) including AusLAB data; and
- any other informal databases.

1.40 Prior to commencing the project, the researcher must:

- seek HREC approval for the protocol and supporting documents;
- discuss project requirements with the data custodian;
- complete a *PHA* application form; and
- send the completed form to Health and Medical Research for approval.

1.41 The *PHA* approval letter must be submitted to the RGO as part of the governance review. Further information on the provisions of the *Public Health Act 2005* (Qld), s282 can be accessed at: http://www.health.qld.gov.au/ohmr/html/regu/aces_conf_hth_info.asp

Research involving Access to Coronial Material

1.42 Research involving access to coronial material must be referred to the Queensland Forensic and Scientific Services Human Ethics Committee (FSS-HEC) for ethical and legal approvals. This also applies to clinical research projects where there is a component involving coronial material. In this context, examples of coronial material include:

- tissues from coronial autopsies;
- slides and blocks;
- blood samples;
- autopsy reports; and
- other documents and data relating to coronial material.

1.43 When researchers require access to and use of data and confidential information from coronial autopsies, for the purposes of research, the provision of s53 of the *Coroners Act 2003* must be considered.

1.44 Fees may be levied by FSS-HEC to recover costs associated with ethical review and monitoring of research projects from applicants external to Queensland Health.

1.45 Further information re use of data and confidential information from coronial autopsies, for the purposes of research can be accessed through the *Site Requirements* link under the Forensic and Scientific Services HEC: *Research Involving Material from Coroners' Autopsies: Advice to ethics committees and researchers* website: http://www.health.qld.gov.au/qhcss/qhss/fss/ethics-committee.asp

Research involving Adults with Impaired Capacity to Consent

1.46 Where a person is over the legal age of consent but is unable to provide written informed consent (whether temporarily or permanently), an application to the Queensland Civil and Administrative Tribunal (QCAT) must be undertaken, as well as a *PHA* application, (please see *Public Health Act 2005* section 1.24 – 1.39 above).

1.47 QCAT will accept applications from a CPI relating to multi-centre or single site research. The submission of one application form will cover all current participating Queensland public health system sites, however QCAT must be informed of any additional Queensland public health system sites joining the study after the initial QCAT review. QCAT does not need to be consulted on matters of research involving children.

1.48 Legal advice suggests that doubt exists as to whether a validly appointed substitute decision maker for personal matters, including health care of a person who lacks capacity (the person), can consent on behalf of the person to the disclosure of clinical information for purposes such as research, quality assurance, professional development, teaching and training. This conclusion is based on the premise that research, quality assurance, professional development, teaching and training do not neatly fall within the definition of health care. Therefore, a *PHA* is required to allow the disclosure of the data of the person whose participation in research is consented by the legally authorised representative.

Research involving Aboriginal and Torres Strait Islander Peoples including Coincidental Recruitment

1.49 The provision of this information enables the RGO to determine if the researchers have consulted with Aboriginal and Torres Strait Islander representatives from the communities involved in the research. National guidelines are available to assist researchers in the conception, design and conduct of projects targeting Aboriginal and Torres Strait Islander Peoples Human Research: http://www.nhmrc.gov.au/guidelines/publications/e52

Research that may be exempted from Human Research Committee Ethical Review

1.50 *National Statement* s5.1.22 - Institutions may choose to exempt from ethical review research that:

- is negligible risk research; and
- involves the use of existing collections of data or records that contain only non-identifiable data about human beings.

The *National Statement* s5.1.23 states that *Institutions must recognise that in deciding to exempt research from ethical review, they are determining that the research meets the requirements of this National Statement and is ethically acceptable.*

1.51 Where the HREC Chair, HREC Administrator or RGO is approached for advice on whether a project falls within the definition of research, and does or does not require ethical review, the applicant should be advised to:

- consult the NHMRC *National Statement on Ethical Conduct in Human Research (2007);* and
- provide an outline of the project in writing to the HREC Chair justifying why they are seeking exemption from HREC review.

Quality Activities

1.52 An activity where the primary purpose is to monitor or improve the quality of service delivered by an individual or an organisation is a Quality Assurance activity. Terms such as 'peer review', 'quality assurance', 'quality improvement', 'quality activities', 'quality studies' and 'audit' are often used interchangeably and are considered part of a Quality Assurance program.

1.53 An HREC will frequently be presented with a project that is clearly a Quality Assurance project (QA) However, undertaking a QA does not require HREC Approval even if an ethical opinion is sought. Quality assurance projects should be registered as per the Institutional Clinical Governance process.

1.54 Clinical governance is a requirement of the compulsory National Safety and Quality Health Service Standards and an associated Australian Health Service and Quality Accreditation (AHSSQA) scheme. http://www.safetyandquality.gov.au/wp-content/uploads/2011/09/NSQHS-Standards-Sept-2012.pdf

1.55 Clinical Governance approval is required for these activities, not Research Governance authorisation.

1.56 If an ethical opinion is sought then local institutional practice may include delegating responsibility to:

- a QA/low-risk committee;
- a sub-committee of the HREC;
- the HREC Chair or appropriate HREC member(s); or
- another appropriate committee or individual involved in / responsible for clinical governance.

1.57 If the delegated responsibility sits with a member of the HREC, then the researcher should be advised to liaise with the HREC Chair as to the documentation required, but as a minimum, a cover letter, a description of the project and project documentation that has been registered as

part of the Institution's Clinical Governance process, along with the intended article for publication, should be submitted for review by the HREC Chair. It is not necessary for an LNR Application to be submitted.

1.58 The project is registered on AU RED and given an HREC number but should be categorised as a QA project.

1.59 The HREC Chair will review the submitted documentation and do one of the following:

1.60 appraise the project, and issue a letter stating that it is a Quality Assurance project and does not require full HREC review and give an ethical opinion; or

1.61 appraise the project and require it to be submitted for review by the HREC or LNR Committee. If it is considered that the project is not a QA, or if parts of the project have been conducted outside the scope of a QA, a NEAF or LNR form must be completed and submitted with the application.

1.62 Research governance authorisation is not required unless the project is considered research or has a research component

Presentation of Un-Consented Confidential Information at Conferences or in Journals

1.63 HRECs will often be asked to provide an approval for presentation of un-consented confidential health information for conference presentations or for publication in professional journals. If confidential information is disclosed without the written consent of the person who the data relates, an application under the *Public health Act 2005* should be made.

1.64 A letter from the HREC must be generated.

1.65 This is an example of where the RGO should waive the requirement of SSA form completion.

Clinical Trials

1.66 This section will only appear on the SSA form if s5, Q1: *Clinical Research* has been selected in the NEAF.

Study phase

1.67 The phase of trial is a good indicator of the level of risk involved in the project. This should be used to prompt the RGO to investigate insurance and indemnity arrangements. Generally, the lower the phase of study (i.e. Phase 0, I or II) the greater the risk for study participants and the institution.

Clinical Trial Notification Scheme (CTN) and Clinical Trial Exemption Scheme (CTX)

1.68 The CTN / CTX form is submitted to the Therapeutic Goods Administration (TGA) when a new clinical trial involving an unregistered product or a registered product undergoing trials in a new clinical indication.

1.69 The CTN / CTX form requires sign off by the HHS CE or delegate. The RGO should check that the form has been signed by a representative of the Reviewing HREC and the site PI prior to presenting it to the HHS CE.

1.70 The RGO will ensure that HHS sign off is obtained before returning the form to the site PI. The site PI will return the form to the study Sponsor, who is the last signatory and is responsible for sending the form to the TGA.

1.71 A copy of the TGA accepted form with all the signatures on it should be provided to the RGO by the Site PI to complete their records. This form should be uploaded to *AU RED* by the PI.

Clinical Trials Registry

1.72 Any applicable trials in the USA must be registered and have results uploaded onto www.clinicaltrials.gov, as per s801 of the Food and Drug Administration Amendments Act - known as FDAAA 801, http://clinicaltrials.gov/ct2/manage-recs/fdaaa .

1.73 The *Declaration of Helsinki* (2013), http://www.wma.net/en/30publications/10policies/b3/ Section 9 states: *Every research study must be registered in a publicly accessible database before recruitment of the first subject*.

1.74 Note there are controversies and national divisions over the *Declaration of Helsinki* text. The US FDA rejected the 2000 and subsequent revisions, only recognizing the third (1989) revision, and in 2006 announced it would eliminate all reference to the Declaration. After consultation, which included expressions of concern, a final rule was issued on April 28, 2008 replacing the *Declaration of Helsinki* with Good Clinical Practice effective October 2008. This has raised a number of concerns regarding the apparent weakening of protections for research subjects outside the United States. The NIH training in human subject research participant protection no longer refers to the *Declaration of Helsinki*. The European Union similarly only cites the 1996 version in the EU Clinical Trials Directive published in 2001. The European Commission, however, does refer to the 2000 revision.

1.75 In addition, the International Committee of Medical Journal Editors (ICMJE) has stipulated in order to publish the trial results in one of their journals, the details of a trial should be publicly available in a clinical trials registry prior to recruitment of the first participant. Examples of a publicly accessible clinical trial registry include ANZCTR http://www.anzctr.org.au/ or clinicaltrials.gov

1.76 The Database of Research Activity (DoRA) is not a World Health Organisation (WHO) compliant clinical trial registry and therefore should not be used as an answer to this question. http://www.health.qld.gov.au/ohmr/html/regu/dora.asp

1.77 If the trial is not registered on a publicly available Clinical Trials Registry, the investigator must provide an explanation as to why.

Clinical Trials – Indemnity and Insurance

1.78 The Sponsor of a project indemnifies the HREC and institution against clinical trials claims.

1.79 The Sponsor must have insurance to cover these claims and should provide evidence that they are insured for clinical trials claims.

1.80 Any insurance and indemnity documents submitted to the RGO need to be reviewed to ensure they are adequate for the type of study being undertaken.

1.81 If a Standard Medicines Australia (MA) Clinical Trial Research Agreement (CTRA) or Medical Technology Association of Australia (MTAA) Clinical Research Investigation Agreement (CRIA) is

used, insurance and indemnity arrangements are identified in Schedules 3 & 4 respectively. For sponsored studies, the researcher should also supply a current certificate of insurance to the RGO.

1.82 As a general guide, insurance cover should be at least AUD$10 million per event. The *Certificate of Currency* should be up to date, and the insurance company ideally, should have an Australian office or representative in this country to enable more efficient settlement of claims. Please consult with the HHS Legal Officer or HHS CE on any local policy the HHS has on accepting an insurance certificate from a company that does not have an Australian office.

1.83 Every research project that includes a non Queensland Health entity requires a statement regarding indemnification. In some instances, Queensland Health will accept a mutual indemnification where each party indemnifies its own personnel and site. However, for commercially sponsored research, the Sponsor must provide indemnification to Queensland Health.

1.84 Both MA and MTAA have released two indemnity forms:

- Standard Form; and
- HREC Review Only form.

1.85 These should be used without alteration. Queensland Health does not accept any other form of indemnity without formal legal review.

Research Study Agreements, Clinical Trial Research Agreements (CTRAs) and Contracts

1.86 All research projects that involve parties outside of Queensland Health require some form of contractual agreement to cover matters such as Confidentiality, Intellectual Property, ownership of data, insurance and indemnity.

1.87 A suite of pre-agreed contracts for various levels of projects are available. An explanation of these is in the table below:

Name of Agreement	Situation for Use	Available from
Student Deed Poll	Undergraduate students on placement in Queensland Health institutions, undertaking research (low risk and non interventional) that is part of their educational curriculum or training. No other contract is required for research. May be used by PhD students depending on the level of risk and potential for commercialisation of intellectual property of the project.	Signed with the Institution prior to commencing placement. http://www.health.qld.gov.au/sop/
Student Non Commercial Research Agreement	Used by PhD students or university staff or academics undertaking research involving resources from within the Queensland Health institutions. Phase 0-III	Contact HMR for the contract. Will require legal review at the HHS and University.
MA CTRA – Standard	Used for commercially sponsored phase 0-IV Clinical Trials where the	Medicines Australia website:

Form	Sponsor undertakes all responsibilities for the conduct and ongoing management of the project.	http://medicinesaustralia.com.au/issues-information/clinical-trials/clinical-trials-research-agreements/
MA CTRA – CRO	Used for commercially sponsored phase 0-4 Clinical Trials where a contract research organisation has been engaged to manage the study in Australia.	
MA CTRA Observational / Phase IV studies	Used for commercially sponsored observational or phase IV studies.	
MA CTRA - CRG	Used for clinical trials that are not commercially sponsored, being undertaken by collaborative groups (Investigator Initiated).	
MTAA Standard CRIA	Use for sponsored clinical investigations involving new technologies.	Medical Technology Association of Australia website: http://mtaa.org.au/policy-initiatives/clinical-investigations

1.88 The MA and MTAA CTRAs describe the terms and conditions of conducting a study, including roles and responsibilities of stakeholders, payments, intellectual property, indemnity, insurance and compensation.

1.89 If these Agreements are used without alteration, Queensland Health will accept them without the requirement for further legal review.

1.90 If amendments to the standard terms and conditions of these Agreements are required, those amendments must be made in Schedule 7 (or Schedule 4, depending on the type of Agreement). If any changes are made to the body of the Agreement, those changes will be deemed invalid, and the original text will prevail, as per the header statement on the CTRA.

1.91 Proposed template amendments to the MA CTRAs and MTAA CIRA are negotiated with the Southern and Eastern Border States (SEBS) Committee. Agreed clauses are identified with version details and are forwarded to RGOs from HMR.

1.92 On receipt of an MA or MTAA research contract containing amendments in the appropriate schedule, the RGO should check the version details and wording with the list of agreed clauses provided by HMR. If the amendments in the contract exactly match the amendments provided by HMR, no further additional legal review of the proposed amendments is required.

1.93 The list of agreed Sponsor amendments is available on this website: http://www.health.qld.gov.au/ohmr/documents/Schedule_7_Clauses.pdf Only the names of the company and version details of the amendments are published. Details of the amendments are *commercial-in-confidence* and are not publicly available.

1.94 All other non standard CTRAs not approved for use by Queensland Health e.g. other investigator initiated research and student research contracts must be reviewed by the HHS Lawyer (for single site studies) or a Queensland DoH approved external legal panel firm (multi-centre studies).

1.95 If your HHS does not have a lawyer or you are part of the DoH, you should check whether the CTRA has been reviewed by an HHS lawyer at another site (contacts details for all Queensland public health system lawyers can be obtained at: http://qheps.health.qld.gov.au/lalu/pdf/qh_lawyers.pdf.

1.96 If amendments have not been previously reviewed on behalf of the Queensland Health then seek advice from your HHS legal advisors who will assess if the contract can be reviewed by their unit or if there is a need to brief an external legal firm (panel firm contracted to Queensland Health for assessment of CTRAs).

Parties to a Contract

1.97 The parties to a contract must be properly identified to ensure the correct legal entity is bound by the contract. The various HHSs are now separate legal entities and must be identified accurately in each CTRA; this includes the correct name, ABN and address.

1.98 [Name of HHS] [Name of Hospital or Institution] ABN [Insert ABN of Institution], of [Street address of Institution]. Please go to the following web link for more information on HHS ABNs http://www.health.qld.gov.au/ohmr/documents/regu/hhs_abn.pdf.

1.99 External entities (including universities, research institutes or other government entities) are not considered supporting departments and are required to enter into an agreement with the HHS / DoH to conduct research within Queensland Health.

Intellectual Property Considerations

1.100 The RGO, in consultation with the HHS CE or HHS lawyer should consider whether the intellectual property arrangements for the research project are consistent with Queensland DoH and HHS Intellectual Property Policy and Intellectual Property Health Service Directive (2013). For further information, contact the Intellectual Property Officer at Health and Medical Research on:

T: 07 3328 9862,

E: ip_officer@health.qld.gov.au; or go to the website at

W: http://www.health.qld.gov.au/ohmr/documents/qh_ip_policy.pdf

Biosafety, Chemical and Radiation Safety

1.101 Information provided by the researcher in this section is to demonstrate to the RGO that biosafety, drug committee and radiation safety approvals have been obtained where necessary.

1.102 Some types of research projects (such as research involving gene therapy), necessitate review and / or approval by an Institutional Biosafety Committee (IBC), and the NHMRC Cellular Therapies Advisory Committee (CTAC).

1.103 Where a project requires compliance with the Australian Radiation Protection and Nuclear Safety Agency (ARPANSA) Code, a medical physicist report will be required. Section 2.1.6 of the *ARPANSA Code on Exposure of Humans to Ionizing Radiation for Research* states that *a researcher must obtain an independent assessment or verification by a Medical Physicist.*

1.104 The relevant Radiation Safety Officer in each HHS can arrange a Medical Physicist to review research protocols and provide a report. They can be contacted through the local Nuclear Medicine Department.

Resources and Budget Information

Departments & services involved in the research

1.105 The RGO must assess, from the information given in the governance application, which departments (main and supporting) are involved in the study and to what extent. Heads of Department must have been consulted and must agree to the project being undertaken in their department. This may be demonstrated by their signature on the SSA form or any other written acknowledgement of their support of the study.

Study Budget at the Site

1.106 The researcher must provide a study budget to the RGO which identifies the source of funding for a project and the annual or participant costs associated with the study. If there is no funding allocated to the project and the researcher wishes to use the HHS staff and resources free of charge, the researcher must report the use of In-kind support and the amount (in dollar terms) from the HHS. The information provided in this section will also assist RGOs provide data for the annual Chief Scientist report.

Site Finance Management

1.107 The provision of this information enables the RGO to identify whether all research costs are covered by the sponsor and if not, how the HHS will benefit from the non-funded research and from which cost centre those costs will be recovered.

1.108 It also allows the RGO to consider the adequacy of the local facilities nominated for the research and to ensure the additional time and resources spent by the researchers have been identified and are appropriate.

1.109 The RGO should consider the advice of Department Heads and Business Managers for the following:

- budget – is identified and is appropriate, adequate and available;
- cost implications – services provided within operating budget or at a stated / agreed cost;
- any additional / hidden costs to the HHS / site from participating in the new research project;
- availability of any extra support required by research participants, for example, reimbursement of transport costs, etc; and
- whether the HHS / site has the appropriate resources to recruit the targeted population.

Finance Authorisation

1.110 The signature of the local Director of Finance or delegate indicates the study budget has been reviewed and approved. This requirement is consistent with the obligations of financial management under the *Financial Accountability Act 2009.*

1.111 Where there are resource demands for a Queensland public health system department, the researcher is to discuss what the funding and resource requirements are and cost these accordingly. The Director of Finance or delegate must sight and consider the implications for the site budget before giving authorisation.

1.112 It is not the responsibility of the RGO to obtain the signature of the Director of Finance or delegate.

1.113 Local policy and procedures will determine whether a HoD or a Business Manager / designated Finance Officer can sign the Financial Authorisation section. In may be determined that the HoD signs off on kind support only research.

Funds management

1.114 Under the *Financial Accountability Act 2009*, the HHS must be able to account for all funds being managed internally. Completion of this section informs the RGO, HHS Finance Officer or relevant Research Finance Officer who to invoice and which cost centre the money is going to for the duration of the project. Details should include:

- cost centre and / or internal order number of accounts where research funds are to be managed; and
- account details of the external organisation that will receive and manage the funding for the study, including the contact person / CRA;

Database of Research Activity (DoRA)

Purpose

1.115 The Database of Research Activity (DoRA) is a publicly accessible, searchable internet website which extracts and automatically downloads research data from *AU RED* and presents it in a format to allow researchers and other interested public stakeholders to search for and view summary level information about research being conducted in Queensland Health.

1.116 The searchable database includes Queensland Health's authorised human research and is designed to facilitate greater collaboration and communication between researchers, improve community access to research information and raise awareness about the benefits of health and medical research.

1.117 Sections 20.1 – 20.10 (in the SSA form) and section 11.1 – 11.10 (in the LNR SSA form) will be automatically populated from previous sections of the forms. Researchers will be asked if they have the authority to consent for the release of the data and if so, to give consent for the release of the data.

1.118 This section of the SSA form is mandatory (the researcher will not be able to finalise the form until this question is answered) and the researcher is advised to consult early with any sponsors to ensure this question does not hold up finalisation of the SSA form.

Declarations

1.119 By signing the Declarations section, a researcher or HoD is confirming that they are aware of and accept their roles and responsibilities with regards to the conduct and completion of research at the site.

Declarations from Investigators and Site Coordinator

1.120 All researchers whether PI or Associate Investigators at the site should sign the declaration to acknowledge their responsibilities under the study protocol HREC Approval and governance authorisation.

Declarations from Head of Department or Delegate where the Research Project will be Conducted

1.121 Researchers should have a signed declaration from the HoD or service areas where resources are required to conduct the study, prior to submission of the SSA form. This declaration is an indication to the RGO and CE that the HoD support the conduct of the study in their department.

1.122 It is not the responsibility of the RGO to obtain the signatures of the Finance Officer, HoD or Heads of Supporting Departments.

Declarations from Head of Department or Delegate providing Support and/or Services to the Research Project

1.123 The provision of this information enables the RGO to determine under what conditions institutional departments can provide support for the research project. It is highly recommended that researchers contact the relevant supporting departments within an institution (e.g. Pathology, Pharmacy, Radiology, Allied Health etc) prior to HREC submission, to ensure that the services can be provided by the nominated department.

1.124 Where an external (non Queensland Health) party is contributing to the research (e.g. tertiary institution), they cannot be considered as a supporting department but must be viewed as an external entity and there must be a research contract in place between Queensland DoH or the HHS and the external party.

SECTION 2: Processing Of Research Governance Applications

New Applications

2.1 A completed governance application should be submitted by the PI responsible for the overall conduct of the research project at the site.

2.2 It is the responsibility of the Site PI to ensure that the completed governance application contains all the essential elements when submitted to the RGO. This includes all attachments as listed in the SSA Checklist.

2.3 New applications for governance review must be submitted using the *Online Forms* SSA form (unless specifically negotiated with the RGO) accessed through http://www.ethicsform.org.

2.4 The RGO must register all applications on *AU RED* within two business days of submission of the application.

2.5 When registering an application, the RGO must check that all data from the SSA form and the supporting documents are uploaded into *AU RED* using the submission code supplied by the researcher, and that the application is valid.

2.6 In line with the parallel approval process, if all documents apart from the HREC Approval Letter are present, the review may commence. Validation of the application will be completed on receipt of the HREC Approval Letter.

2.7 Site-specific information should be included in the local version of the participant information sheet and consent form (PICF) for the study, such as:

- the address and telephone number of the site;
- contact details for the local investigator(s) and, if applicable, other staff such as:
  - research nurses; and
  - emergency contacts if appropriate;
- contact information for complaints.

2.8 The research content of the PICF may not be changed by the researcher or RGO after HREC approval unless this is first submitted to the Reviewing HREC as an amendment and the amendment is approved by the Reviewing HREC.

2.9 It is the responsibility of the site PI with the consent of the participant, to make arrangements for notifying other pertinent health care staff, who may be caring for the participants, about the proposed research.

Entry of Applications on *AU RED*

2.10 When registering a governance application into *AU RED*, the HREC Reference Number, which is on the SSA form under Section 1, must be entered in to *AU RED*. Once the HREC reference number is entered, the application can be registered and *AU RED* a unique identifying SSA number will be generated by *AU RED*.

Uploading Applications into *AU RED*

2.11 SSA forms are completed in the *Online Forms* website.

2.12 In *AU RED*, click on the *Upload Online Form Data* button on the *Details* page, and enter the submission code which is printed on the bottom right hand side of each page of the SSA form. If there is no submission code on the SSA form, it means a draft version of the document has been submitted (the word *Draft* will be present as a watermark across the form) and the RGO must contact the researcher and ask them to create a submission code for their SSA form. The researcher must notify the RGO of the submission code, and resubmit the form with a submission code.

2.13 Any signatures collected on the Draft SSA form will need to be re-collected on the final version with the submission code. Alternatively, the researcher may submit a signed statement declaring that no changes have been made to the form since collecting the signatures on the *Draft* version.

2.14 The RGO must also ensure that when uploading the SSA Form, all fields in *AU RED* are populated. In particular, the following tabs in *AU RED* should be checked:

- *References* tab: Mode of Study select if the study is Statewide, National or International;
- *Details* tab: Ensure there is a short title in the appropriate box, and that the Low Risk Review, Student, CTN and CTX boxes are correctly ticked; and
- *Contacts* tab: as a minimum, the Study Sponsor, site name, site PI and site contact person should be uploaded.

2.15 Researchers must upload electronically, all supporting documentation (e.g. Participant Information sheets, CTN/CTX forms, contracts, insurance and indemnity documentation etc) through the Online Forms website when completing their SSA form. This ensures that the RGO receives and has an electronic record of all the supporting documentation submitted.

2.16 If supporting documentation has not been uploaded against the SSA form, the application should be deemed *Invalid*. The RGO must contact the researcher to notify them that ongoing review of the site specific application will not proceed until supporting documentation has been uploaded. The only exception to this is when research governance review is undertaken in parallel with HREC review, and the HREC Approval Letter has not yet been issued. However, the HREC Approval Letter must be uploaded against the SSA form, by the PI, once it has been received, and prior to site authorisation.

Uploaded Supporting Documents

2.17 If the applicant has attached electronic copies of their supporting documentation to their SSA form, these documents will automatically be uploaded into *AU RED* when the submission code is entered. To view the uploaded document, click on the magnifying glass icon next to the document in the *Uploaded Documents* column in the *Checklist* tab and follow the prompts.

2.18 If the researcher uploads a newer version of an electronic supporting document to their SSA form, they should notify the RGO that the revised version is available. The revised version can then be uploaded to the *Application Checklist* tab simply by clicking the refresh version icon next to the current version of that document in the list of *Documents Checked In*. *AU RED* will keep a copy

of all document versions uploaded (note that if a document with the same file name as a previously loaded document is uploaded, it will overwrite the original document).

2.19 If the researcher uploads an entirely new document into the SSA form after the RGO has uploaded it, the RGO will need to upload the online form data again (using the same submission code unless the form itself has been modified) in order to pull the new document into *AU RED*.

Governance Application Validation

2.20 A valid governance application is one which is deemed complete by the RGO (contains all relevant signatures and with supporting documentation uploaded against the *Online Form*). The clock is started when the application is made valid in *AU RED*.

2.21 If supporting documentation has not been uploaded by the researcher, the application is deemed invalid and the researcher must correct this before further review of the application is undertaken.

2.22 All signature pages in the SSA form should have the same submission code as the remainder of the document. If the submission codes are different on any pages, a written statement should be submitted by the researcher explaining why the submission codes are different, and outlining any changes made to the document which caused the changes to the submission code. Depending on the type of changes that have been made, verification that the relevant signatories to the SSA form are aware of and approve of the changes may also be required.

2.23 As a general guide, the governance application is accepted as valid if it meets all the following criteria:

- all questions and sections in the SSA form have been completed (unless prior agreement with the RGO and an SSA form is not required);
- a copy of the HREC approval letter and approved protocol have been attached (note if governance review is undertaken in parallel with HREC review then the HREC approval letter will be the final document submitted to the RGO) or the *PHA* Approval letter;
- the application has been signed by the Site PI and all Associate Investigators;
- the application has been signed by supporting HoD;
- the budget section has been completed, including the details of any in-kind support given by Queensland Health;
- all HREC approved study documents, and new site specific documents have been electronically uploaded against the SSA form, including the protocol, HREC approved Master PICF and Site Specific PICF;
- a short CV (less than two pages) for all site investigators; and
- other supporting documents that may be applicable: CTN/CTX forms, contractual agreements, indemnity forms, biosafety/chemical and/or radiation safety approvals, and *PHA* and/or QCAT approvals have been attached and uploaded electronically to the SSA form in *Online Forms*.

2.24 The researcher is responsible for uploading all approved documentation to the SSA form or in the case of a waiver of the requirement of an SSA, copies must be provided in whichever format the RGO requests.

2.25 When the governance application is valid, the 25-day clock on *AU RED* is started and the RGO acknowledges receipt by writing to the Site PI. When governance is undertaken in parallel with HREC review the final document that will be submitted to the RGO is the HREC Approval Letter.

2.26 If the application is invalid, the Site PI is notified of the reason. When an invalid governance application is received by the RGO, the Site PI is requested to supply the missing information. The 25 day clock does not begin until a valid application has been received.

2.27 All research governance reviews exceeding 25 days post validation date are monitored by the Department of Health to assess if any remedial actions are required to be implemented. Aggregated metrics regarding Governance review are available to the public.

Withdrawal of Applications

2.28 Where the Site PI decides not to proceed with the research project at that site, they may withdraw the governance application. A request to withdraw the research project from governance review is made in writing to the RGO.

SECTION 3: Research Governance Review and HREC Approval

General Guidance

3.1 Neither the Reviewing HREC nor the local institutional HREC will be required to review or note the governance application prior to granting ethical approval.

3.2 The governance application must be submitted to the RGO. Compulsory supporting documentation includes a copy of the HREC approval letter, HREC approved research protocol, the HREC application form (NEAF or LNR) and the Master and Site Specific PICFs.

3.3 In reviewing the Master and Site Specific PICFs, the RGO should check the footers and version details. The Site Specific PICF footer should contain a reference to the Master PICF version details with additional version information inserted to identify this version of the Site Specific PICF.

3.4 Approval and authorisation of the governance application by the HHS CE or delegate is contingent upon HREC approval of the research. In the parallel review process, the HREC Approval letter will be the last supporting document that the researcher will provide.

3.5 The RGO may communicate any concerns regarding any identified local circumstances relevant to the ethical review to the Reviewing HREC.

Central Coordinating Service Early Alert

3.6 For multi-centre research studies booked through the Central Coordinating Service (CCS), the relevant RGOs (i.e. those from participating sites that are covered by the HREC review as identified by the researcher in the CCS Booking Form) will receive an early alert of the research study. This will be in the form of an email giving the short title of the study, the CPI, the Reviewing HREC, the HREC number and date of ethical review.

3.7 This is an early alert only to inform the RGO that a study which may be conducted at their site is about to undergo ethical review. The RGO is not required to do anything at this stage.

SECTION 4: Granting Institutional Authorisation to Conduct Research

General Guidance

4.1 Only the HHS CE or delegate can authorise a research project to commence within, or in association with their HHS.

4.2 Once the RGO has completed the assessment of the governance application, they will provide a recommendation to the HHS CE or delegate. This may include (but is not limited to) the following documents to authorise commencement of the project at the HHS site:

- the governance application form;
- the HREC approved research protocol;
- PICF – Master and local site versions;
- the HREC approval letter;
- *Public Health Act 2005* approval letter;
- CTN/CTX form, plus CTX Approved Usage Guidelines if applicable (signed by the HREC Chair or other HREC Committee member only);
- insurance and indemnity forms; and
- Clinical Trial Research Agreement (if applicable).

4.3 Any conflict of interest pertaining to researchers, institutions, HREC members & all other stakeholders should be considered in accordance with Implementation Standard 5: Conflict of Interest in Research 2010, Research Management Policy 2012 and Research Management Directive 2013.

Research Governance Office/r Review

4.4 It is expected that the RGO will conduct their assessment in an efficient and timely manner. A 25-day review clock, that commences when a valid governance application is received, is to be adhered to for the completion of the governance review and authorisation.

4.5 The RGO should forward the application for the HHS CE or delegate authorisation when:

- the governance application review is complete; and
- the RGO has provided their recommendation on the governance application – including clearance from the HHS Lawyer, Queensland DoH Legal Unit or an external legal provider if a non standard contract has been used.

Guidance for Potential Waiving of the Requirement to Complete a Site Specific Assessment (SSA) Form

4.6 Some research projects may be eligible for consideration of a modification to the process of research governance by waiving the need to complete an SSA form.

4.7 The decision to waive completion of the SSA form is made by the RGO at each site, after discussion with the researcher and HHS CE or delegate.

4.8 Waiving of the requirement for the SSA form does not remove the requirement for research governance or HHS CE authorisation to conduct the project.

4.9 Notification to the researcher to discuss the potential for the waiving of the completion of the SSA form is via the HREC Approval letter. The HREC Administrator may modify the HREC Approval letter to suggest the researcher liaise with RGOs at each research site to discuss the possibility of a modified research governance process. It is the RGO at each site who will make the determination of eligibility for the modified process.

4.10 There are two separate procedures in place where the requirement to complete an SSA form for each participating site may be waived - with the agreement of the RGOs at each participating site:

- *Minimum impact, minimum resource use research* (e.g. hanging a recruitment poster for an HREC Approved research project, but where all follow up is outside the Queensland public health system). Projects like this may be eligible for waiving the completion of the SSA form.
- *Minimum resource use research* – where the total contribution from the Queensland public institution is minimal – e.g. 10 minute survey targeting six or less staff at each site. Projects like this may be eligible for a modified review process so that only one SSA form is submitted for all participating sites.

Waiving Research Governance for Research Requiring a *PHA* (Non Queensland Health Employees)

4.11 Where HREC approval is granted to a research project where the only resource impact is the data custodian releasing data to a researcher who is not an employee of Queensland Health, there is no requirement for research governance authorisation, as there is a legislative basis for the release of the data, i.e. the *PHA*.

4.12 The Data Custodian has to agree to the release of the data and may charge a fee if the resource impact is too great.

4.13 A register of all *PHA* applications is maintained by the Department of Health.

4.14 The HREC approval may be from a Queensland or interstate NHMRC registered HREC.

Waiving Research Governance for Research Requiring a *PHA* (Queensland Health Employees)

4.15 Where the researcher is an employee of Queensland Health, the RGO may waive the requirement for completion of an SSA form, and can issue an Authorisation Letter provided they have the *PHA* Approval Letter. Please refer to *Guidance for the Potential Waiving of SSA Form* above.

HHS CE or Delegate Authorisation

4.16 The HHS CE or delegate may either support the application and sign the authorisation to commence the research project, or refuse the application on site specific grounds.

4.17 When the CE has made the decision to authorise or not authorise the project, the RGO records the decision in *AU RED* and creates the appropriate letter of notification to the PI.

Notification of the Decision to the Site Principal Investigator

4.18 The RGO is responsible for notifying the site PI of the decision of the HHS CE (or delegate). This is in the form of a standard letter noting the decision, accompanied by the signed CTN/CTX Form, CTX Approved Usage Guidelines (if applicable) and the CTRA (where applicable).

4.19 Initial notification of the HHS CE or delegate authorisation to the researcher may be via email.

4.20 The RGO is required to enter the decision of the HHS CE or delegate into *AU RED*. (i.e. whether or not the project has been authorised to commence at the site). All documentation relating to the governance review for each research project (including, evidence of final ethical opinion of Reviewing HREC, final protocol, copy of CTN form, clinical trial agreement etc.) must be kept on file in a secure and confidential manner, by the relevant RGO.

4.21 If the HHS CE or delegate has not authorised the commencement of the study, the RGO will inform the researcher of the reasons and work with the researcher and CE or delegate to possibly enable the study to be undertaken at a later date.

Exceptional Circumstances Review

4.22 There may be exceptional circumstances where as a matter of public policy, and in the national interest, it is essential that an application is reviewed urgently to allow a health-related research study to commence as quickly as possible. Such circumstances could include the urgent need for research data where there is an imminent threat to public health. There could also be a need to capitalise on a unique opportunity for significant research where there is only a limited time to consider participation.

4.23 An application for review under exceptional circumstances is never justifiable solely on the grounds of a researcher's claim to the need for urgent review of their project based on failure to meet deadlines.

Procedure

4.24 Applications submitted for review under exceptional circumstances should contain:

- a completed application form;
- copy of the HREC approval letter;
- study protocol and supporting documentation; and
- a request for exceptional circumstances review in writing containing the reason for requesting review under exceptional circumstances and the justification for the request.

4.25 Review of the application will follow normal processes, bearing in mind the time specific circumstances.

4.26 The HHS CE or delegate may grant authorisation, under exceptional circumstances for a study where:

- a certified HREC has approved the application and it appears to conform to the requirements of the institution / HHS; or
- a clinical need necessitates urgent authorisation of the application.

4.27 In some exceptional circumstance cases, the PI may be exempt from completing an SSA form, subject to local research governance requirements. This decision will be made between the RGO

and HHS CE or delegate and communicated to the researcher. All authorisation documents should be signed off by the HHS CE or delegate in accordance with normal authorisation procedures. At this stage the research may commence.

SECTION 5: Amendments to Authorised Research

General Guidance

5.1 This section refers to amendments (including requests for time extensions) to those research projects which have been granted authorisation by an HHS CE or delegate. Where an amendment to a research project is proposed, the following procedures should be followed.

Amendments to the Research Project which may affect the Ongoing Ethical Acceptability of the Project

5.2 As a condition of ethical approval, the Reviewing HREC requires the CPI/PI to request approval for proposed amendments to the research project which may affect its ongoing ethical acceptability. Examples of amendments requiring approval by an HREC include changes to the following:

- The safety, physical and/or mental integrity of the participants in the trial;
- The scientific value of the trial; or
- The quality or safety of any investigational medicinal product used in the trial.

5.3 Amendments approved by the Reviewing HREC may commence upon receipt of an HREC approval letter, provided they do not affect the ongoing acceptability of the study at the study site. However, the site RGO must still be notified of the amendment, even if it has already been implemented.

5.4 Where the amendment request may alter the ongoing acceptability at the study site, each local site PI must notify the RGO, in writing. The amendment may not be implemented at that site until authorisation has been granted by both the HHS CE or delegate and the Reviewing HREC.

5.5 Only those amendments which affect the ethical acceptability of the research project require submission to, and review by the Reviewing HREC.

5.6 Amendments are submitted to the Reviewing HREC Administrator and may be approved out of session. The site PI should submit a copy of the approval letter for the amendments to the RGO.

5.7 The outcome of the HREC review and any revised documentation pertaining to the research project must be submitted by the site PI to the relevant RGO for the HHS/site record.

Amendments to the Research Project which only Affect the Ongoing Site Acceptability of the Project

5.8 Amendments to the research project which may impact upon the suitability of the research to be conducted at that site will necessitate a submission, in writing, to the RGO.

5.9 Amendment requests for an authorised research project may be submitted directly to the RGO (by-passing the HREC) only when the amendment requires:

- no change to the authorised application form (do not redo the SSA); and
- a change to one or more of the following sections of the SSA form:
  - Section 4 – Training;
  - Section 6 – Anticipated start and finish dates (HREC must be told if the duration of the study exceeds the approved time frame);

- Section 8a(ii), b(ii) or c(ii) – Medicines Australia Form of Indemnity - Standard Form;
- Section 8a(iii) b(iii) or c(iii) – Evidence of adequate insurance cover;
- Section 8d – Medicines Australia Standard Clinical Trial Agreement;
- Section 11 – Departments and services involved in the research;
- Section 13 – Queensland Health account number(s) / cost centre details;
- Section 14 – Finance Authorisation; or
- Section (a – f) – Declarations and authorisations.

5.10 The RGO will determine whether authorisation from the HHS CE or delegate is required to implement the amendment at that site. If the RGO determines that authorisation from the HHS CE or delegate is not required, the RGO will notify the site PI, in writing, that authorisation is not required for the amendment to be implemented at the site.

5.11 If the RGO determines that authorisation from the HHS CE or delegate is required, the RGO will forward the relevant documentation to the HHS CE or delegate for authorisation. The RGO will then notify the site PI as to whether or not authorisation has been granted by the HHS CE or delegate for the amendment to be implemented at that site.

5.12 It is the responsibility of the site PI to ensure they have received notification of authorisation of the amendment by the RGO, prior to implementation of the amendment at that site.

5.13 If, in the course of reviewing an amendment application from the PI, the RGO notes that amendments to the research project may impact on the ongoing ethical acceptability of the project (for example, amendments to the recruitment process), and an amendment request has not been submitted to the HREC, the RGO will notify the site PI that HREC review of the amendment will be required prior to the proposed amendment being authorised and implemented at the site. The RGO may discuss aspects of the proposed amendment with the HREC and vice versa. For multi-centre studies approved under the single ethical review process, the local PI will notify the CPI of the requirement for ethical review by the Reviewing HREC.

5.14 The RGO will record the outcome of the amendment review in *AU RED*.

5.15 The RGO must keep all documentation relating to the amendment for each research project on file in a secure and confidential manner, at the relevant HHS site.

Amendments to the Research Project which may affect both the Ethical Acceptability and Site Acceptability of the Project

5.16 Where a proposed amendment to the research project may affect both the ethical acceptability and site suitability of the project, the CPI must submit an amendment request to the Reviewing HREC. The Reviewing HREC will review the amendment request according to standard procedures and will notify the CPI in writing of its decision.

5.17 Once HREC approval has been given for the amendments, copies of the HREC approval letter, a cover letter and all relevant updated documents with track changes must be uploaded onto the *Online Forms* website against the original SSA form by the Site PI prior to submission to the RGO for authorisation to implement the amendment at the site.

5.18 The Chair and HREC Administrator will assess if an amendment can be approved prior to the next full HREC meeting and if so it must be noted on the agenda.

5.19 The site PI may not implement the amendment until the RGO has provided written notification that the amendment has been authorised at the HHS site.

Amendments to the Research Project that do not Affect either the Ethical Acceptability or Site Acceptability of the Project (e.g. typographical errors, addition to study team)

5.20 Amendments that do not affect either the ethical acceptability or site acceptability of the project should be submitted in hard copy to the Reviewing HREC Administrator by the CPI. These should include a cover letter from the CPI, stating the changes and reasons for changes, and all relevant updated documents with tracked changes. All altered documents should have updated version numbers and/or dates. All submitted documents, including the cover letter, must be uploaded into *Online Forms* by the CPI prior to submission.

5.21 The amendments should also be submitted to the local RGO by the site PIs. These should include a cover letter from the PI, stating the changes and reasons for changes, and all relevant updated documents with tracked changes. Again, all submitted documents should be uploaded by the Site PI and attached to the original SSA.

Extension of a Research Project to an Additional Site

5.22 For those studies conducted under CTN/CTX schemes, the TGA and Reviewing HREC must be notified of the new site/s by completion of a new CTN/CTX form with the new site information included.

5.23 If the original Reviewing HREC is not certified to approve multi-centre research in the study field, or the project was originally a single site project which is now adding a new site, the CPI will be required to submit the study to a certified HREC for approval. The CPI will be required to contact the CCS to determine which HREC will review the application.

5.24 The Reviewing HREC will notify the CPI once approval is granted.

5.25 The CPI will notify the local PI who will then apply to the local RGO for HHS authorisation.

5.26 The research will not be able to commence at each additional site until each respective HHS/site has granted authorisation.

Urgent Safety-Related Measures

5.27 Where it is necessary to eliminate an immediate hazard to the research participants, amendments to the research study may be implemented without prior HREC review and authorisation from the HHS CE / delegate (if necessary).

5.28 The Sponsor of the study must be notified immediately by the PI if the protocol amendment is due to urgent safety issues at the site.

5.29 As soon as possible, the implemented amendment should be submitted to the HREC and RGO.

SECTION 6: Monitoring of Research that has been given Institutional/HHS Authorisation

General Guidance

6.1 A Reviewing HREC should establish with RGOs at the sites for which they have monitoring responsibility, the process and level of institutional monitoring of the project, and the method of providing feedback from the Institution's RGO to the Reviewing HREC.

6.2 Individual institutions or HHSs that agree to allow the conduct of research at their sites must have a documented safety reporting procedure in place.

6.3 Participating sites must have a mechanism for the review of SAEs occurring at their Institution, which is external to and separate from the HREC. Institutional RGOs must recognise their role in monitoring safety and protocol compliance at a site, and implement a feedback reporting process to the Reviewing HREC.

6.4 The DoH endorses two guidance documents for the reporting of adverse events (AEs) and SAEs – the NHMRC Australian Health Ethics Committee (AHEC) *Position Statement on the Monitoring and Reporting of Safety in Clinical Trials (2009),* and the *NHMRC Framework for Monitoring Guidance for the National Approach to Single Ethical Review for Multi Centre Research (2012):* http://www.nhmrc.gov.au/_files_nhmrc/file/health_ethics/hrecs/reference/090609_nhmrc_position_statement.pdf, http://hrep.nhmrc.gov.au/toolbox/guidance-multi-centre-research .

Clinical Trials

6.5 NHMRC Australian Health Ethics Committee (AHEC) Position Statement on the Monitoring and Reporting of Safety in Clinical Trials (2009) states:
For each trial, investigator/researcher must also provide:

2.1 In accordance with individual institutional requirements NB: institutions should seek to keep individual requirements to minimum or utilise such requirements in a highly targeted manner if these are particular safety concerns	to institution (or HREC as specified by institution) — AEs or SAEs occurring at their site(s)
2.2 In a prompt manner to HREC responsible for trial	— information which materially impacts the continued ethical acceptability of the trial or — information that requires, or indicates the need for, a change to the trial protocol, including changed safety monitoring in the view of the investigator or sponsor.
2.3 At least six-monthly to HREC	— listing of all SUSARs, Australian and

responsible for trial	international, occurring with a compound — including sponsor and investigator comment as to whether action is planned for the trial on the basis of the reports — EU format is acceptable.
2.4 At least annually to HREC responsible for trial	— an updated Investigator Brochure, or — an EU ASR (or similar format report), or — current, approved Product Information (PI), if appropriate (e.g. in a study for a product approved in Australia or where an Investigator Brochure is no longer maintained) — other reports consistent with section 5.5.5 of the *National Statement* and Good Clinical Practice (GCP) as adopted by the Therapeutic Goods Administration (TGA).

Progress Reports

6.6 Institutions are responsible for the ongoing monitoring of the ethical conduct of research projects for which they have granted ethical approval (*National Statement* s5.5). As a minimum, the institution will require at regular periods, (at least annually), progress reports from investigators on matters including:

- Progress reports to date or final reports in the case of completed research;
- Maintenance and security of records;
- Compliance with the approved protocol; and
- Compliance with any conditions of approval.

6.7 The Reviewing HREC recommends in the HREC Approval Letter, the frequency, type and format of reporting and monitoring which reflects the degree of risk of the research.

6.8 Annual reports for research projects are due on the anniversary of the HREC Approval date.

6.9 The local site PIs will send a progress report to the CPI (if multi-centre research) and local RGO. The CPI will coordinate the reports and send them to the Reviewing HREC. The HREC will send written notification of the HREC review of the progress report to the CPI.

6.10 In very specific cases of high risk research, the HREC may recommend in its letter of approval that the RGO coordinate on-site monitoring at recommended intervals or randomly throughout the research project. The RGO will provide advice to the HREC.

6.11 If an HHS / site considers that it cannot comply with the monitoring recommendations made by the HREC, then it should not grant authorisation of the research at the HHS / site.

6.12 The coordination of on-site monitoring by the RGO involves making the necessary arrangements for appropriate personnel (internal and external to Queensland Health) to conduct the monitoring activity within the given timeframe.

6.13 On-site monitoring, coordinated by the RGO, may include attention to:

- auditing / inspection of research conduct in compliance with the agreed protocol and conditions of approval, including consent documentation, current number of participants, commencement / completion / withdrawal dates;
- auditing / inspection of research conducted in accordance with ICH GCP;
- auditing / inspection of data storage and security; and
- whether or not consent was obtained from participants, for interviews (or other forms of feedback).

Tracking of Medical Devices

6.14 Tracking of medical devices will be as per the TGA requirements and Australian Medical Devices Guidelines.

6.15 Medical Device TGA SAE Forms and guidelines:

- http://www.tga.gov.au/docs/pdf/forms/iris_mdir03b.pdf ;
- http://www.tga.gov.au/docs/pdf/forms/iris_udir03c.pdf
- http://www.tga.gov.au/docs/pdf/devguid11.pdf

6.16 Device identifiers are placed into patients medical notes and manufacturers are required to maintain a tracking system.

Suspension or Withdrawal of Authorisation for a research project

Suspension or Withdrawal of HREC Approval

6.17 Where the Reviewing HREC considers it appropriate that the adverse event/s and/or progress reports require the immediate suspension or discontinuation of the ethical approval of the research project, the HREC should immediately notify the CPI who will notify the local Site PIs, who will then notify their local RGOs of this decision. This should be followed by a notice in writing, from the Reviewing HREC, within three working days.

6.18 An investigator cannot continue the research if ethical approval has been suspended or withdrawn and must comply with any special conditions imposed by the HREC.

6.19 Upon receipt of the HRECs decision, in writing, to suspend or withdraw ethics approval, the RGO must promptly advise the HHS CE or delegate to suspend or withdraw authorisation to conduct the research at the HHS sites. In such circumstances, the RGO will be required to immediately inform the Site PI of the suspension or withdrawal of authorisation to conduct the study at the site. This notification must be confirmed in writing within three working days.

6.20 If research is being conducted under the CTN or CTX scheme, it is a breach of the TGA legislation (*Human Research Ethics Committees and the Therapeutic Goods Legislation)* to continue without HREC or institutional approval.

Suspension or Withdrawal of Authorisation by the HHS CE at a Site at which the Research is being Conducted

6.21 Where the HHS CE or delegate is satisfied that circumstances have arisen where it is no longer appropriate to conduct a research project at the site/HHS, the HHS CE may suspend or withdraw his/her authorisation to conduct the research at that site/HHS.

6.22 In such circumstances, the RGO is required to immediately notify both the site PI and the Reviewing HREC.

6.23 The RGO must consult with the Reviewing HREC first, to ensure the safety and welfare of research participants that may be involved in the research. This notification must be confirmed in writing within three working days.

6.24 For multi-centre studies the local PI must notify the CPI of the date and reason for the suspension or withdrawal of authorisation at the site. The CPI must then notify the Reviewing HREC.

6.25 An investigator cannot continue with the research if the HHS CE or delegate has suspended or withdrawn authorisation for the research to be conducted at that site.

6.26 It is the responsibility of the RGO to update *AU RED* accordingly.

Study Closure/Termination at a Site

6.27 Where an authorised research project is to be closed at a site, the site PI must notify the Reviewing HREC in writing. The PI will also be required to notify the RGO in writing,

6.28 Where a research project at a site is prematurely terminated or suspended by the site PI, the HREC and RGO should be promptly informed and provided with a detailed written explanation of the circumstances.

6.29 *AU RED* should be updated accordingly by both the HREC Administrator and RGO.

SECTION 7: Levy for Governance Review

Schedule of Fees

7.1 Governance review of commercially sponsored studies is subject to a fee.

7.2 Fees may also be levied by Queensland Health to recover costs associated with ethical review and monitoring of research projects from applicants external to Queensland Health.

Background

7.3 In 2007, the revisions of the *National Statement* and *The Code* clearly identified the roles and responsibilities of institutions, researchers and review bodies in the conduct of research. In particular, these documents place the onus on institutions to take clearer overall responsibility for research governance.

7.4 The revised *National Statement* and *Code* advise institutions to have appropriate research governance processes in place to allow the monitoring of research to be undertaken.

7.5 Queensland Health has implemented a policy of charging commercial sponsors for HREC review, independent expert review and governance review of research protocols.

Payment of Fees

7.6 It is the responsibility of the Site PI to provide the RGO with details of the Sponsor organisation to whom the invoice will be sent.

7.7 Invoices will be sent to the Sponsor / CRO by the HHS / site Finance Department as per local business practice.

7.8 The HHS CE or delegate may withhold final research authorisation until the invoice has been paid.

7.9 If cheques are received by the RGO they must be forwarded to the Finance Department in line with local administrative procedures.

What does the Fee for Governance Review by a RGO Cover?

7.10 The governance review fees enable the RGO to fulfil their duties as follows:

- funding and managing the RGO, including the costs for equipment, furniture and stationery;
- assessing the completeness and appropriateness of the research project based on the information provided in the governance application;
- provide timely recommendation to the HHS CE or delegate on the authorisation of research projects at the HHS;
- liaising with other HHS sites, Reviewing HRECs and HHS Administration on governance matters;
- liaising with researchers regarding governance submissions, requests for clarifications, responses and incomplete submissions;
- reviewing amendments and local SAEs;
- training researchers in the preparation and submission of governance applications;

- coordination for the monitoring of authorised research protocols, requesting reports, organising audits and contacting non compliant researchers;
- invoicing sponsors for governance fees, receipting, reconciliation, follow up of unpaid invoices; and
- RGO professional development.

SECTION 8: Handling Complaints

General Guidance

8.1 A framework for dealing with allegations of research misconduct is outlined in the Code. A number of people within a site/HHS have responsibility for investigating and resolving allegations of research misconduct, such as, the HHS CE or delegate, Heads of Department, research supervisors and researchers. The site/HHS should ensure that all personnel are aware of their responsibilities.

8.2 Sites/HHSs must make public, the process for receiving and resolving allegations of research misconduct. This should be consistent with *The Code*; the Queensland Health documents *General Principles for Handling Research Complaints* and *Complaints Process for Research Misconduct*.

Procedure for handling complaints concerning the governance review process, including the HHS CE or delegate rejection of an application

8.3 The site PI may appeal the decision of the governance assessment.

8.4 Any concern or complaint about the governance review process should be directed in writing to the attention of the RGO.

8.5 The RGO will notify the institutional CE of any complaints received as soon as possible. The institutional CE will inform the RGO of any complaints received as soon as possible.

8.6 The RGO will investigate the complaint and its validity, and make a recommendation to the institutional CE or delegate on the appropriate course of action.

8.7 If the complainant is not satisfied with the outcome of the RGO review, then they can refer the complaint to the HHS CE or delegate, or request the institutional CE do so.

8.8 The RGO will provide to the HHS CE all relevant information about the complaint/concern.

8.9 The HHS CE will determine whether there is to be any further investigation of the complaint.

8.10 If it is decided that further investigation is warranted, then the HHS CE will convene an investigating committee to review the complaint, ensuring that both the complainant and the RGO are afforded the opportunity to make submissions. In conducting its review, the investigating committee shall be concerned with ascertaining whether the RGO acted in accordance with the *National Statement*, the *Standard Operating Procedures for Queensland Health Research Governance Officers*, or otherwise acted in an unfair or biased manner.

8.11 The decision of the investigating committee will be final.

8.12 Appeals against HREC decisions will be dealt with as specified in the HREC SOPs.

Procedure for Handling Complaints about the Conduct of an Authorised Research Project

8.13 As per *The Code*, the institutional CE will nominate advisers in research integrity to advise possible complainants about research conduct issues and explain the options open to persons considering making, or having made an allegation.

8.14 The institutional CE will nominate a Designated Person for handling research complaints, including research misconduct.

8.15 Any concern, allegations or complaints about the conduct of a project must be reported, in the first instance, to the Reviewing HREC's institutional Designated Person for handling research complaints, including research misconduct.

8.16 Any complaints received must also be forwarded to the Reviewing HREC who will enter the complaint details into *AU RED*. The local RGO (where the complaint applies) will also enter the details into *AU RED* against the applicable SSA number.

8.17 Initially, complaints should be forwarded by the Designated Person to the relevant department to be dealt with at departmental level.

8.18 The departmental decision will be reported back to the Designated Person, the HREC Administrator and the local RGO.

8.19 The Designated Person will review the departmental decision and make a recommendation to the HREC on the appropriate course of action.

8.20 If the complainant is not satisfied with the outcome of the Designated Person's investigation, then they can refer the complaint to the institution's CE or delegate.

8.21 For allegations not resolved at departmental level and appeals, the Reviewing HREC's Institutional CE or delegate will establish an investigating committee; nominating three independent individuals, who do not have any conflict of interest in the case and have appropriate expertise to evaluate the research issues and review the case.

8.22 The decision of the investigating committee will be final.

8.23 Participant Information Sheet and Consent forms must include details of whom to contact with regard to making a complaint.

8.24 All complaints will be acknowledged within seven days.

8.25 The complainant will be advised of the decision within 30 days.

SECTION 9: Education and Training of Research Governance Officers

Essential Reading

NHMRC National Statement on Ethical Conduct in Human Research (2007)

NHMRC and Universities Australia Australian Code for the Responsible Conduct of Research (2007)

Therapeutic Goods Administration Note for Guidance on Good Clinical Practice (CPMP/ICH/135/95) (2000)

Public Health Act 2005 (Qld), Part 4 Division 1 s280

Guidelines under Section 95 of the *Privacy Act* (Cth) *1988*

Guidelines under Section 95A of the *Privacy Act* (Cth) *1988*

Information Privacy Act 2009 (Qld)

Queensland Health Intellectual Property Directive, 2013

Queensland Health Research Ethics and Governance Directive, 2013

Finance Management Practice Manual

Coroners Act 2003 (Qld), s.53

Hospital and Health Boards Act 2011 (Qld) Part 7

SECTION 10: Storage and Retention of RGO Records and Documentation

General Guidance

10.1 The Queensland Health Strategic Records Management Team have advised that until such a time that the Retention Disposal Schedule has been approved by Queensland State Archives, all governance records and associated documentation should be held by HHS/sites indefinitely.

10.2 Further information can be obtained from the Queensland Health Strategic Records Management Team on 07 3239 0928,or http://qheps.health.qld.gov.au/srmt/home.htm

Archiving Completed Studies

10.3 Once a study has been finished and logged in *AU RED* as being *Completed and Archived*, the project and all accompanying documentation may be removed from the RGO Office and archived.

10.4 Research projects should be archived according to the year the study is completed.

10.5 Within each archive box, projects should be stored in numeric order according to the year they were authorised.

10.6 A record of the archive box identifier is entered into *AU RED*, on the *References* tab for the study, in the *Archive Number* field.

Appendix 1

Multi-Centre v Single Centre – Guidance for Queensland Health HREC Administrators and Research Governance Officers

These examples are to help you decide if research can be reviewed under the National Approach or the Queensland Single Ethical Review Process.

	Example	***AU RED* classification** (Enables data collection re multi-centre studies)	**Contact the CCS**	**Rationale**
1	The study is at your **public** health site and one or more other **public** health sites in Queensland	Multi-centre	Yes	The study is multi-centre - staff in more than one Queensland Health site are involved
2	The study is at your site only, but also in Melbourne and Sydney **public** hospitals	Multi-centre	Yes	This study may be able to be reviewed under the NMA model.
3	The study is at your **public** site only in Australia, but at least one site internationally	Multi-centre	Yes	The study may be extended to more than one site/centre in Queensland Health.
4	The study is to be carried out at more than one site within different Queensland Health HHSs in Mental Health / Community / Dental Services etc	Multi-centre	Yes	The study is multi-centre - staff in more than one Queensland Health site are involved
5	The study is at your **public** site only and one or more **privates** site in Australia and at one or more sites internationally	Multi-centre	Yes	The study may be extended to more than one site in Queensland Health.
6	A researcher wants to send questionnaires out to staff in two or more HHSs.	Multi-centre	Yes	Staff in more than one district or site are involved
7	A registry study using data linkage is to be undertaken where the data is to be obtained from more than one Queensland Health data source	Multi-centre	Yes	Staff in more than one Queensland Health site are involved
8	A registry study is to be conducted at your site using Queensland Health data.	Single site`	No	The study is only using one data source. The HREC Administrator needs to be certain that no other sites outside of the HREC jurisdiction will be involved i.e. that there is no potential for the study to become multi-centre.
9.	A university based researcher wishes to access Queensland Health data from one	Single site	No	External party accessing Queensland Health data

	Queensland Health database, but all data analysis undertaken in university			
10	The study is at your public health site and at a non public site eg University, Private Hospital, GP clinic	Multi-centre	Yes	The study may be extended to more than one site/centre in Queensland Health.
11	The study is at your site and other sites in your district	Multi-centre	Yes	The study is multi-centre - staff in more than one Queensland Health site are involved
12	The study is at your **public** health site and another hospital or community health centre in your HREC ethical jurisdiction.	Multi-centre	Yes	The study is multi-centre - staff in more than one Queensland Health site are involved
13	The study is at your **public** site only and no other sites in Queensland, Australia or internationally.	Single site	No	The HREC Administrator needs to be certain that no other sites outside of the HREC jurisdiction will be involved i.e. that there is no potential for the study to become multi-centred.
14	The study is not being undertaken at your public health site but has been sent to your site for review	Check category for multi-centre		Depends if it is single or multi site but should be referred to certified HREC
15	The CPI/PI is jointly employed between a Queensland Health site and a different site (e.g. University or private institution) but the study is only being conducted at a Queensland Health Site and the University still requires their own HREC approval.	Single Site	No	Only requires allocation to certified HREC if the HREC opinion is going to be accepted by an institution that would not usually accept the reviewing HREC approval.