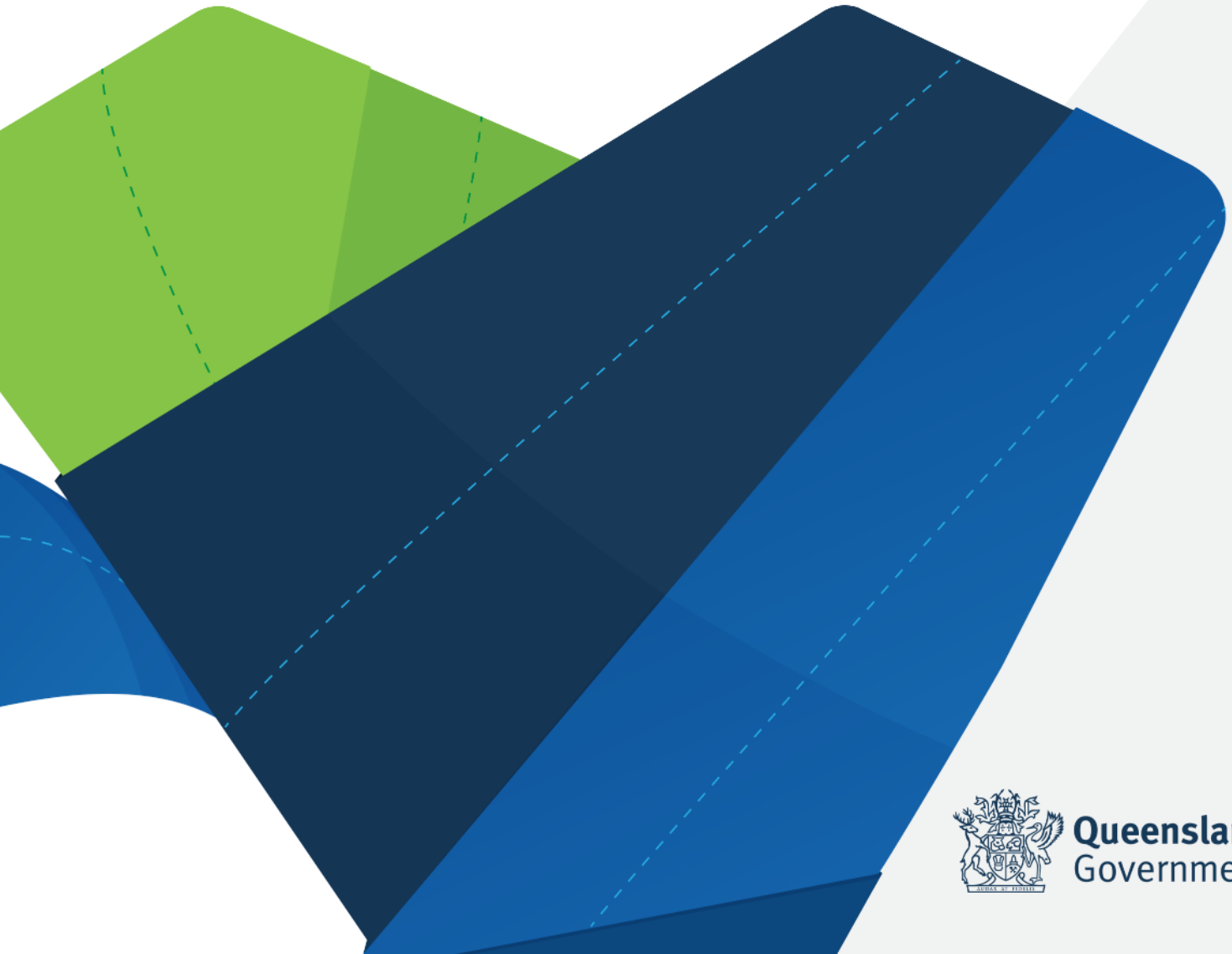
Researcher User Guide

Queensland Health July 2023



Queensland Government

1 INTRODUCTION AND SUMMARY

This guide is designed to help researchers understand how to get approval for research projects that involve patients, staff, data, or resources from Queensland Health in Australia.

Getting approval involves two main steps:

Ethics Review: Your project needs to be reviewed by a Human Research Ethics Committee (HREC). They'll look at whether your project is ethical and scientifically sound.

Governance Requirements: You also need to complete research governance requirements. This involves dealing with the business, legal, and logistical parts of your project to get permission to do the research at a specific location.

Research governance is important for every Hospital and Health Service to make sure they're following all the relevant laws and site-specific requirements.

The results from the HREC review and research governance assessment are given to the Chief Executive (CE) or their delegate at the institution where the research is to be conducted. These documents cover all aspects of the project and help the CE decide whether to authorise the research at the site.

You can submit applications for ethics and governance at the same time, but governance authorisation can only be granted after HREC approval. Importantly, you can't start your research at a site until research governance authorisation is granted.

Please note that research governance requirements don't apply to healthcare evaluations or non-research activities that have been granted an exemption from HREC review. However, local institutional clinical governance requirements may still apply - for instance, an assessment by a quality assurance committee might be required.

How to Apply

To apply for approval, you'll need to submit your project to the HREC for review. They'll look at the ethical and scientific aspects of your project. You'll also need to complete the research governance requirements, which involve dealing with the business, legal, and logistical parts of your project.

Once you've completed these steps, the results will be given to the Chief Executive (CE) or their delegate at the institution where the research is to be conducted. They'll use these documents to decide whether to authorise the research at the site.

Remember, you can't start your research at a site until you've been granted research governance authorisation.

What Happens Next?

After you've submitted your applications and they've been reviewed, you'll receive the decision. If your project is approved, you can start your research. If it's not approved, you'll receive feedback on what needs to be changed or improved.

Remember, conducting research is a big responsibility. Make sure you're following all the relevant laws and guidelines, and always consider the ethical implications of your work.

Changes During the Project

Sometimes, you might need to make changes to your research project after it's been approved by the HREC and authorised by the relevant Chief Executive. This could be because of new information, unexpected results, or feedback from participants. If you need to make changes, you'll have to submit a modification request. This request will be reviewed by the HREC and the research governance office to make sure the changes are ethical and don't affect the project's approval status.

Reporting and Monitoring

Once your project is underway, you'll need to keep track of its progress and report any issues or problems. This is called monitoring. You'll need to submit annual progress reports, final reports when your project is finished, and report any serious incidents or problems that happen during the project.

Closing Your Project

When your research project is finished, you'll need to formally close it. This involves submitting a final report to the HREC and the research governance office. They'll review your report and, if everything is in order, officially close your project.

Getting Help

If you're ever unsure about something or need help, don't hesitate to ask. There are plenty of resources available to help you navigate the research approval process. You can reach out to the HREC or the research governance office or check out the resources on the Queensland Health website.

Remember, the goal of all this is to ensure that research is conducted ethically and responsibly. It's a lot of work, but it's worth it to make sure that your research benefits people and contributes to our understanding of health and medicine. Good luck with your project!

Frequently Asked Questions

What if my project involves multiple sites?

If your research project involves multiple sites, you'll need to get authorisation from each one. Each site has its own research governance office/r that will review your project. You'll need to submit a separate application to each site.

What if my project involves children or young people?

If your project involves children or young people, there are additional ethical considerations to take into account. You'll need to make sure that your project is designed in a way that respects their rights and welfare. The HREC certified to review children's research will review your project to make sure it meets these standards.

What if my project involves Aboriginal or Torres Strait Islander people?

If your project involves Aboriginal or Torres Strait Islander people, you'll need to follow the guidelines for ethical conduct in Aboriginal and Torres Strait Islander health research. These guidelines are designed to ensure that research involving Aboriginal or Torres Strait Islander people is conducted respectfully and responsibly. More details are included in this document.

What if I need to change my project after it's been approved?

If you need to change your project after it's been approved, you'll need to submit a modification request. The HREC and the research governance office/r will review your request to make sure the changes are ethical and don't affect the project's approval status.

What if something goes wrong during my project?

If something goes wrong during your project, you'll need to report it as soon as possible. This could be a serious incident, an unexpected result, or a problem with the conduct of the project. The HREC and the research governance office will review the issue and decide what action needs to be taken.

Conclusion

Conducting research is a big responsibility, but it's also an opportunity to make a real difference. By following the guidelines in this guide, you can ensure that your research is conducted ethically and responsibly. Remember, the goal is to contribute to our understanding of health and medicine in a way that respects the rights and welfare of all participants. Good luck with your project!

DEFINITIONS and ABBREVIATIONS

Please note: Not all the definitions listed here may be used in this document, but they may be used generally in research and are included to provide clarification to researchers.

Adverse event (AE)	Any untoward medical occurrence in a patient or clinical trial participant administered a medicinal product and that does not necessarily have a causal relationship with this treatment. *Ref: Safety monitoring and reporting in clinical trials involving therapeutic goods. See web links section of this document for further information.*
Amendment	Any change to a study which has received ethics approval.
Applicant	The Principal Investigator (PI) for single site studies and Coordinating Principal Investigator (CPI) for multi-centre studies.
Associate Investigator (AI)	An investigator who assists with the conduct of a study under the direction of the Principal Investigator (PI). Synonymous with Sub-Investigator.
Australian Code for the Responsible Conduct of Research	The document which establishes in Australia a framework for responsible research conduct that provides a foundation for high-quality research, credibility and community trust in the research endeavour. For further information, refer to the relevant entry in the web links section of this document.
Certified HREC	An HREC which has had its processes assessed and certified under the NHMRC National Certification Scheme.
Clinical Research Associate (CRA)	A Sponsor or Contract Research Organisation (CRO) representative engaged to monitor clinical trials. The CRA ensures compliance with the clinical trial protocol, checks site activities, reviews Case Report Forms and acts as a communication conduit between sites and the Sponsor.
Clinical Research Coordinator (CRC)	The person designated by the PI to be responsible for coordinating the conduct of a research study, under the

	direction and supervision of the PI. Synonymous with Site Coordinator.
Confidential information as per *Hospital Health Boards Act* (HHB)	In accordance with the HHB Act, Part 7, section 139 Confidential information means— (a) information, acquired by a person in the person's capacity as a designated person, from which a person who is receiving or has received a public sector health service could be identified or (b) information accessed by a prescribed health practitioner under section 161C (2).
Contact Person	The person designated by the PI to be responsible for liaising with the HREC/Research Governance Officer (RGO).
Contract Research Organisation (CRO)	An organisation (commercial, academic, or other) contracted by the Sponsor to perform one or more of 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 PIs (see PI) participating in the research, and who are listed on the CPI's HREC application. For single site studies, the terms CPI, Coordinating Principal Researcher, Site PI and PI are all synonymous.
Department of Health (DoH)	The Department of Health (DoH) manages the health system in Queensland.

Ethics Review Manager (ERM)	Ethics Review Manager (ERM) is a secure web-based research application system used by researchers to submit and process HREC and RGO applications. It has two components: Researcher Portal used by researchers to submit a HREC or RGO application, amendments, and reports for HREC or RGO review and approval. Administrators Portal used by HREC member/Administrators, RGOs and approved administrative staff to process HREC and RGO applications, amendments, and reports.
ERM Applications	ERM Applications is an online system that enables users to complete their applications for research ethics and governance review electronically. The system hosts a licensed copy of the HREA, as well as the site-specific assessment forms for the public health systems of Queensland and Victoria.
ERM Project ID	The ERM Project ID is a unique number given to projects and is generated when an applicant creates an application. It remains constant for the life of the application and is transferred to any sub-form created from the *parent* form.
Forensic and Scientific Services (FSS)	Conducts forensic, public health and environmental testing and research. FSS is part of Health Support Queensland in the Queensland Department of Health and has its own ethics committee to review research proposals. For further information please refer to the FSS in the Web Links section of this document.
Good Clinical Practice (GCP)	An international ethical and scientific quality standard for designing, conducting, recording and reporting trials that involve the participation of human subjects. May also be referred to as International Conference on Harmonisation (ICH) GCP. For more information, please refer to the GCP entry in the web links section of this document.
Health information held by a health agency as per *Public Health Act* 2005 (QLD) PHA	In accordance with the PHA, Health information held by a health agency: means information held by the agency about a person's health or the provision of a health service to a person or

	information about a person's health or the provision of a health service to the person obtained by the agency under this Act or another Act or information about a person's health or the provision of a health service to a person held or obtained by an approved operator under chapter 6, part 3A for the purpose of keeping the Notifiable Dust Lung Disease Register or for chapter 6, part 4, information about a person's health or the provision of a health service to a person held or obtained by a contractor for the contractor to keep the Queensland Cancer Register and includes information about a person who is deceased.
Hospital and Health Boards Act 2011 (HHB Act)	An 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 confidentiality.
Hospital and Health Service (HHS)	A Hospital and Health Service (HHS) established under section 17 of *the Hospital Health Boards Act 2011* (Qld) (HHB Act).
Human Research Ethics Application (HREA)	A streamlined and contemporary ethics application that uses dynamic content and guidance to assist researchers consider and address the principles of the *National Statement*. There are two formats for this document – the NHMRC version and the ERM version. Both formats are acceptable for HREC review. The ERM version is the preferred form for use in Queensland Health HRECs. The NHMRC version of the form must be transferred to the ERM version to enable it to be uploaded to ERM.
Human Research Ethics Committee (HREC)	A Human Research Ethics Committee (HREC) is a committee registered by the NHMRC and constituted under the guidance of the National Statement to conduct the ethics and scientific review of a human research project. 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. HRECs are also required to consider and apply the core values, principles and themes as guided by the *Ethical conduct in research with Aboriginal and Torres Strait Islander Peoples and communities: Guidelines for researchers and stakeholders* as the basis when assessing research proposals that include Aboriginal and Torres Strait Islander Peoples' participation.
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 HREC Chair in matters related to the activities of the Committee. Synonymous with HREC Coordinator.
Low and Negligible Risk (LNR) Research	Research 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. For more information, please refer to the *National Statement,* Section 2.1.6.
Multi-Centre Research (MCR)	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. For more information, please refer to the Certification Handbook – *National Certification Scheme of Institutional Processes related to the Ethical Review of Multi-centre Research*, November 2012, p 1 (NHMRC website)
National Mutual Acceptance (NMA)	The national mechanism to allow specific types of multi-centre research to be reviewed by a Certified HREC and for that HREC review to be accepted across all public health institutions within participating jurisdictions. For the website link, please refer to the web link pages in this document.
National Statement on Ethical Conduct in Human Research (2007, Updated 2018)	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.
Negligible Risk Research	Research 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. For more information, please refer to the *National Statement,* section 2.1.7.
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 is one that can be linked with other data so it can be confirmed that they are about the same data subject, although the person's identity remains unknown. For more information, please refer to the *National Statement,* chapter 3.1.
Opt Out process	A participant recruitment process where information is provided to the potential participant regarding the research and their involvement and where their participation is presumed unless they take action to decline to participate.
Office of Research and Innovation (ORI)	Previously known as HIIRO - the Health Innovation and Investment Research Office
Personal Information (as per *Information Privacy Act 2009*)	In accordance with the *Information Privacy Act 2009:* 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.
Public Health Act 2005 (PHA)	The *Public Health Act 2005* provides the basic safeguards necessary to protect public health through cooperation between the state government, local governments, health care providers and the community.
Principal Investigator	The Investigator responsible for the overall conduct of the research study at an individual site. For multi-centre studies, a

(PI)	PI does not have CPI responsibilities. For single site studies, the terms CPI, Coordinating Principal Researcher, Site PI and PI are all synonymous. For more information, refer to the ORI webpage *For Researchers*. (Refer to web links page in this document).
Quality Assurance Activity (QA)	A non-research clinical governance activity that is a requirement of the compulsory *National Safety and Quality Health Service Standards* and associated *Australian Health Service and Quality Accreditation Scheme.* May include patient satisfaction surveys, surveillance and monitoring and clinical audits. There is no RGO involvement if an HREC has granted an exemption from HREC review. For more information, please refer to the links in the web link page in this document.
Quality Assurance (QA) Quality Improvement Activity (QIA)	QAs are defined as the evaluation of current practice to monitor its effectiveness, or benchmarking current practice against a procedure, standard or guideline. These projects are registered with the institution's Patient Safety and Quality Office. If there is intent to publish the outcomes, and an HREC opinion is required for publication purposes, QAs are generally considered as *Exempt from HREC Review* when appraised by the HREC Chair – unless there is a research component to the project (in which case they may be considered LNR research and will require HREC review). Projects that are exempt from HREC review do not require research governance processing.
Queensland Clinical Trials Coordination Unit (QCTCU)	The Queensland Clinical Trials Coordination Unit (QCTCU) sits within ORI and encompasses the former Research Ethics and Governance Unit of the Office of Research and Innovation (ORI).
Queensland Health	Queensland Health is a department of the Queensland Government which operates and administers the public health system. It consists of the DoH and 16 HHSs.
Registered HREC	A Human Research Ethics Committee that is registered with the NHMRC, to review research proposals that involve human participants, in accordance with the requirements of the *National Statement on Ethical Conduct in Human Research.*

	A registered HREC that holds no certification under the NHMRC National Certification Scheme may not review multi-centre research unless by special arrangement with all participating parties.
Re-identifiable Data	Data from which identifiers have been removed and replaced by a code, but it remains possible to ascertain a specific individual by using a relevant code or linking different data sets. For more information, please see the *National Statement*, chapter 3.1.
Research Authorisation	Authorisation is issued by the DoH or HHS Chief Executive (CE) or delegate to allow research to commence at a site within their jurisdiction once the RGO provides a recommendation to the DoH or HHS or delegate that all ethical and governance requirements have been met. 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 review days from receipt of a valid research governance application.
Research Governance	An institution's research governance framework defines the way all staff involved in research share responsibility and accountability for the institution's research being conducted according to appropriate regulatory, ethical and scientific standards and within the levels of acceptable institutional risk. (*ref: NHMRC Research Governance Handbook).*
Research Governance Office(r) (RGO)	The Research Governance Office(r) (RGO) function is responsible for: assessing the site-specific aspects of research applications making recommendations to the DOH/HHS CE or delegate as to whether a research study should be granted authorisation to commence at that site monitoring authorised research at the site to ensure it meets appropriate standards (Research Governance).
Research Governance process	The Research Governance process is an assessment separate from the ethics review of the research project, and based on information provided in the governance application. The RGO assesses the appropriateness of site involvement, resource

	implication, expertise and experience of researchers, compliance in relation to relevant laws, policies and codes of conduct, consent, biosafety, professional standards, radiation safety, legal requirements and onsite monitoring. A recommendation for authorisation (or not) is made to the DOH/HHS CE or delegate. Once authorised, the study may commence at that institution/HHS.
Reviewing HREC	An HREC that has been allocated to review research studies.
Sixty (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.
Twenty-Five (25)-day clock	The period of 25 review days allowed for the deliberation of a research governance decision on an application.
Serious Adverse Event (SAE)	Any adverse event/adverse reaction that results in death, is life-threatening, requires hospitalisation or prolongation of existing hospitalisation, results in persistent or significant disability or incapacity, or is a congenital anomaly or birth defect. For more information: Queensland Health complies with the recommendations in the NHMRC's *Safety monitoring and reporting in clinical trials involving therapeutic goods* Please refer to the relevant link in the Web Link pages in this document.
Single Site Research	Research to be conducted at one site only.
Site Coordinator	The person designated by the PI to be responsible for coordinating the conduct of a research study, under the direction and supervision of the PI. Synonymous with CRC and study coordinator.

Site Specific Assessment (SSA) Form	A tool to assist RGOs in the research governance process documenting the level of support and suitability of a research study to be conducted at a site, irrespective of whether the study is multi-centre or single site.
Site Specific Governance Amendment	An amendment request for an authorised research study that may be submitted by the applicant to the RGO only (thereby bypassing the HREC). For example: changes to site contracts and changes to participating site staff other than the PI.
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 at a site, after site authorisation has been granted
Sponsor	An individual, company, institution or organisation which takes responsibility for the initiation, management, and/or financing of research. *ref: TGA Clinical Trials Handbook.* An organisation which administers research funds obtained through a grant or other process, but which has no other responsibility for the research project is not the Sponsor of the project. For further information, please refer to the TGA Clinical Trials Handbook link in the Web Links section of this document.
State Specific Modules	Victoria and Western Australia 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 more information, please refer to the State Specific Modules entry in the Web Links section of this document.
Stop Clock facility:	For research applications, the time when the administrative clock is stopped, pending a satisfactory response from the applicant to a written request for further information or clarification from the HREC or RGO. The clock is re-started when a satisfactory response has been received and the review can continue.

Study Site	Means the location(s) under the control of the institution where the study is conducted.
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. A study can have different Site Start Dates.
Sub-Investigator	An investigator who assists with the conduct of a study under the direction of the PI. Synonymous with AI.
Suspected Unexpected Serious Adverse Reaction (SUSAR)	A SUSAR is defined as an untoward and unintended response to a study drug, which is not listed is the applicable product information, and meets one of the following serious criteria: results in death, is life-threatening, requires hospitalisation or prolongation of an existing hospitalisation, results in persistent or significant disability or incapacity, or is a congenital anomaly or birth defect.
Therapeutic Goods Administration (TGA)	The Therapeutic Goods Administration (TGA) is the agency responsible for regulating therapeutic goods in Australia. For more information, please see the relevant entry in the Web Links section of this document.
Validation	A preliminary administrative review carried out by an HREC Administrator to verify that all required documentation for a research application has been 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 a HREC Administrator. For research requiring review at a full HREC meeting, the relevant HREC meeting closing date.

Table of Contents

Web Links Referenced in this Guide.

Name of Document	Web Link
(TGA) Access to Unapproved Products	https://www.tga.gov.au/accessing-unapproved-products
Australian Commission on Safety and Quality in Healthcare	https://www.safetyandquality.gov.au/ For more information: Clinical Governance: https://www.safetyandquality.gov.au/our-work/clinical-governance/clinical-governance-standard Measurement and Quality Improvement: https://www.safetyandquality.gov.au/standards/nsqhs-standards/clinical-governance-standard/patient-safety-and-quality-systems/action-18
Australian Teletrial Program	https://australianteletrialprogram.com.au
Australian Radiation Protection and Nuclear safety Agency (ARPANSA)	https://www.arpansa.gov.au/
Department of Education (Qld) Research	https://education.qld.gov.au/about-us/reporting-data-research/research
ERM Application Forms website	https://au.forms.ethicalreviewmanager.com/
Health Translation Queensland Research Passport Agreement	Health Translation Queensland | research, passport (healthtranslationqld.org.au)
Good Clinical Practice (ICH GCP)	https://ichgcp.net/ https://www.tga.gov.au/publication/note-guidance-good-clinical-practice
Gunning Fog Readability Index	http://gunning-fog-index.com/
Hospital and Health Boards Act 2011	https://www.legislation.qld.gov.au/view/html/inforce/current/act-2011-032
Medical Technology Association of Australia Clinical Investigation Research Agreements	Clinical Investigation Research Agreements - MTAA
Medicines Australia Clinical Trial Research Agreements	https://www.medicinesaustralia.com.au/policy/clinical-trials/clinical-trial-research-agreements

(NHMRC) Australian Code for the Responsible Conduct of Research	https://www.nhmrc.gov.au/about-us/publications/australian-code-responsible-conduct-research-2018#block-views-block-file-attachments-content-block-1
(NHMRC) Ethical Considerations in Quality Assurance and Evaluation	https://www.nhmrc.gov.au/about-us/resources/ethical-considerations-quality-assurance-and-evaluation-activities
(NHMRC) Guidance on Ethical Conduct in Research involving Aboriginal and Torres Strait Islander Peoples.	Ethical conduct in research with Aboriginal and Torres Strait Islander Peoples and communities: Guidelines for researchers and stakeholders
(NHMRC) HREA website	https://hrea.gov.au.
(NHMRC) HRECs - Certified	https://www.nhmrc.gov.au/research-policy/ethics/national-certification-scheme-ethics-review-multi-centre-research
(NHMRC) HRECs - Registered	https://www.nhmrc.gov.au/research-policy/ethics/human-research-ethics-committees
(NHMRC) PICF templates	https://www.nhmrc.gov.au/research-policy/ethics/ethical-issues-and-resources
(NHMRC) Research Governance Handbook	https://www.nhmrc.gov.au/sites/default/files/documents/reports/research-governance-handbook.pdf
(NHMRC) Safety monitoring and reporting in clinical trials involving therapeutic goods	https://www.nhmrc.gov.au/about-us/publications/safety-monitoring-and-reporting-clinical-trials-involving-therapeutic-goods
National Mutual Acceptance scheme for single HREC review.	https://www.health.qld.gov.au/hiiro/html/regu/mutual_accept
National Standard Operating Procedures for Clinical Trials, including. Teletrials, in Australia	https://www.health.gov.au/sites/default/files/documents/2021/02/national-standard-operating-procedures-for-clinical-trials-national-standard-operating-procedures-for-clinical-trials-including-teletrials-in-australia.pdf
Public Health Act (PHA) Information	https://www.health.qld.gov.au/hiiro/html/regu/aces_conf_hth_info
Queensland Ambulance Service Research and Data Requests	https://www.ambulance.qld.gov.au/research
Queensland Civil and Administrative Tribunal (QCAT)	https://www.qcat.qld.gov.au/

Queensland Corrective Services Research	https://www.publications.qld.gov.au/dataset/qcs-application-to-conduct-research
(QH) Forensic and Scientific Services Research	https://www.health.qld.gov.au/healthsupport/businesses/forensic-and-scientific-services/research
(QH) ORI Home Page	https://www.health.qld.gov.au/hiiro
(QH) ORI *For Researchers* web page	https://www.health.qld.gov.au/hiiro/html/regu/for_researcher
(QH) HREC Information	https://www.health.qld.gov.au/hiiro/html/regu/hrec_contacts
Protocol Template	CLINICAL TRIAL PROTOCOL AND PROTOCOL AMENDMENT(S) ICH Guideline for Good Clinical Practice | Therapeutic Goods Administration (TGA) https://www.spirit-statement.org/spirit-statement/
(QH) Queensland Public Sector Health System Multi-Site Research Collaboration Agreement	https://www.health.qld.gov.au/hiiro/html/regu/for_researcher
(QH) Research Ethics & Governance Health Service Directive	https://www.health.qld.gov.au/directives/html/a#r
(QH) Research Governance Officers Contact List	https://www.health.qld.gov.au/hiiro/html/regu/info_rgo
(QH) Research Management Policy	https://www.health.qld.gov.au/system-governance/policies-standards/doh-policy
(MA) Teletrials Subcontract (National sites including Qld Health)	https://www.medicinesaustralia.com.au/policy/clinical-trials/clinical-trial-research-agreements/
(QH) Teletrials Information	https://www.health.qld.gov.au/hiiro/html/teletrials
Queensland State Archives Health Sector clinical records retention and disposal schedule	https://www.forgov.qld.gov.au/schedules/health-sector-clinical-records-retention-and-disposal-schedule
State Specific Modules	VIC:http://www.health.vic.gov.au/clinicaltrials/application-instructions.htm#vsm WA:http://www.health.wa.gov.au/researchdevelopment/home/hrec.cfm#ethics
(TGA) *Therapeutic Goods Act*	https://www.legislation.gov.au/Series/C2004A03952

(TGA) Therapeutic Goods Administration	https://www.tga.gov.au
(TGA) Clinical Trials Handbook	https://www.tga.gov.au/resource/australian-clinical-trial-handbook
(TGA) Guidance for Good Clinical Practice	https://www.tga.gov.au/publication/note-guidance-good-clinical-practice
(TGA) TGA Home page	http://www.tga.gov.au/about/about.htm
Universal Trial Number for Clinical Trials	https://apps.who.int/trialsearch/utn.aspx,

2 A Quick Start Guide

2.1 Determining if Your Project Qualifies as Research

Prior to initiating your project, ascertain whether it is categorised as research. Research projects necessitate additional approvals such as ethics approval and governance authorisation. If your project is not classified as research, it won't need to undergo a research approval process. Consult the provided guidance documents if you're uncertain.

2.2 Required Documentation for Ethics Review

Study Plan or Protocol: A study plan or protocol, separate from the application form, is required for all applications.

Participant Information Sheet and Consent Forms (PICFs / ICFs): If your research involves participants or their data, you need their consent. If consent cannot be obtained from each individual, appropriate legislative permission must be identified.

Other Supporting Documentation: Additional supporting documentation, such as advertisements, questionnaires, and data collection forms, must be included with your application.

Other Approvals: If your study involves other institutions or government departments, additional approvals may be necessary.

2.3 Application Forms

HREC Application Form (HREA): All applications for HREC review must be completed using the HREA form, which includes uploading all supporting documents.

Research Governance Application Form (SSA): The SSA form is used for research governance processing and must be completed for each site participating in the research project.

Public Health Act Grant Application: If your research involves the use or disclosure of identifiable information without consent, you'll most likely need to obtain approval via a Public Health Act grant.

Queensland Civil and Administrative Tribunal Application: For clinical trials involving new or off-label uses of drugs or devices, where a participant cannot provide consent, approval may be required to be obtained from the Queensland Civil and Administrative Tribunal.

2.4 Student Research

All students conducting research in Queensland public health institutions require clinical and academic supervisors. If the primary supervisor is not an employee of a Queensland public health institution, the student should nominate an educational supervisor or Student Liaison Officer from within the Queensland Department of Health.

2.5 Project Commencement

A research project may not commence until both HREC approval and research governance authorisation have been obtained. Please note that HREC approval does not equate to

permission to commence a project at a site. Research governance authorisation from the relevant Chief Executive or delegate is required before a project can commence at an HHS.

3 Ethics applications

3.1 Is it research?

The distinction between a research project and a quality improvement project is sometimes difficult. Decision trees have been developed to assist in making this determination. See Appendix 1.

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.

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 ethics opinion is sought. Quality assurance projects should be registered as per the HHS Clinical Governance process. Contact the local Clinical Governance team to discuss requirements.

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. For further information, please refer to the Web Links in this document.

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

The National Health and Medical Research Council (NHMRC) has published a guidance document for ethical considerations in quality activities. Please see the list of web links the list of web links in the beginning of this document and refer to Ethical Considerations in Quality Assurance and Evaluation.

If in doubt, the HREC Administrator for the ethics committee aligned with the institution in which the project will be carried out, may provide additional guidance.

3.2 Before starting.

Before preparing the application, researchers should review the following policy documents:

Queensland Health Research Management Policy (RMP).

The RMP applies to all Department of Health employees, volunteers, contractors, consultants, and external entities who propose to undertake, administrate, review and/or govern human research involving the Department of Health. Please see the list of web links the list of web links in the beginning of this document and refer to Research Management Policy.

Research Ethics and Governance Directive

The Directive applies to all Hospital and Health Services. Please see the list of web links the list of web links in the beginning of this document and refer to Research Ethics and Governance Health Service Directive.

These documents outline the Research Management Framework for the conduct of all research activities within or in association with Queensland Health. The requirements are consistent with the National Health and Medical Research Council (NHMRC) National Statement on Ethical Conduct in Human Research (2007) (Updated 2018) (The National Statement) and the NHMRC and Universities Australia Australian Code for the Responsible Conduct of Research (2007) (The 2018 Code) and relevant State legislation and regulations.

3.3 The ethics application

The HREC application form (HREA)

All applications for a Human Research Ethics Committee (HREC) review of research must be completed on the Human Research Ethics Application form (HREA), irrespective of the level of risk (i.e., Low and Negligible Risk (LNR) research must be submitted using the HREA).

The HREA is available from the Ethics Review Manager (ERM) forms website or the NHMRC website Please see the list of the list of web links in the beginning of this document and refer to either the ERM Application forms, or NHMRC HREA.

Both versions of the form will be accepted for an HREC review as it is the same form, available from different IT platforms. However, all applications for review by a Queensland Health HREC must be made submitted via the ERM website. Applicants must register on the site before they can access forms. Guidance for accessing and navigating the forms is available under the Help tab on the website.

If the NHMRC version of the HREA has been completed, it can be transferred into ERM using the following process:

1. Save the NHMRC HREA as an XML file

2. Log into ERM and import the form using the Import Xml icon in the ERM Action Tiles to complete the import of the XML file.

3. All supporting documents must be uploaded into the ERM HREA for submission.

The HREA has been designed to meet the requirements of the NHMRC “National Statement on Ethical Conduct in Human Research” (2007) (updated 2018).(The National Statement). The National Statement asks the researcher to respond to the fundamental ethical principles and considerations for HRECs and researchers in determining the ethical acceptability of a research study.

Refer to the National Statement when you are preparing your application as it will answer any queries you have about what an HREC will be looking for from the responses you provide. Information icons and prompts throughout the HREA will provide additional guidance.

The HREA builds a customised ethics application form according to the type of research study by disabling questions and sections that are not relevant. You will only see questions

relevant to your research proposal. Responses to questions in the HREA should refer reviewers to the relevant section of the protocol or other supporting documents. Detailed responses in the HREA are only required if the question has not been covered in the project documentation.

Researchers should note that the HREA is an application form only. It is not a study plan or protocol.

3.4 The study plan or protocol

A study plan or protocol is required for all applications – it is the living document for the project and provides the background and justification for the project, details the research aims, hypothesis (if applicable), methodology, risk management including data protection, and statistical analysis. The protocol should be written in such detail that if the researcher is unable to complete the project, another researcher can pick up the protocol and continue the work.

The institution in which the researcher is based may have their own preferred protocol template – check with the HREC Administrator if uncertain. Queensland Health provides a protocol template on its website, which is written for a clinical trial, but which may be modified to fit any type of research project: Please see the list of the list of web links in the beginning of this document and refer to Protocol Template.

All protocols must have a version number and version date. If changes are made to the content of the protocol, both the version number and date should be updated to distinguish one version from the next.

The protocol may not be changed without submitting the proposed changes (i.e. protocol amendments) to the HREC for approval. HREC approval (and subsequent research governance authorisation, if applicable) must be obtained prior to implementing the change to the research. This includes notification to the HREC of any administrative changes (eg correction of typos).

The only exception to this is where participant safety is directly threatened if immediate protocol changes are not implemented. All supporting documentation must be uploaded into the HREA and submitted via ERM. Each document should have version detailed included in the cover page or footers.

Supporting Documentation

All supporting documentation must be uploaded into the HREA and submitted via ERM. Each document should have version details included in the cover page or footers.

Single site:

For single site research, all documents should be submitted for ethics review, with the exception of site-specific documentation required for research governance assessment eg study budgets, contracts and letters of support from relevant Heads of Departments. All documents created specifically for the project must have footers with identifying version details.

Multi-site:

For multi-site research, submit the same documents as for single site research, except where site specific changes will be made to documents (eg PICFs or fliers). In these cases, a Master version of the document should be submitted, with site specific details left blank.

If a document is a Master version, on which a site-specific version will be based, this should be reflected in the footer. Please see the Researcher Tip below.

Please note: For multi-site research, unless otherwise agreed by each RGO, a site-specific assessment form must be created for each participating site. This includes sites that may be in jurisdictions that use a different software system for creating and processing research applications. For sites that do not use ERM, a Minimum Data Form (MDF) may be required to allow creation of the site-specific assessment form Each different software system will require its own MDF. Instructions are in Part 4 below.

4 The Process of Ethics Applications

4.1 Research or Quality Improvement: The Distinction

Occasionally, it can be challenging to differentiate between a research project and a quality improvement endeavour. To aid this judgement, decision trees have been composed, which you can find in Appendix 1.

A Quality Assurance activity is a process where the principal objective is to monitor or enhance the quality of service provided by an individual or an organisation. Terms such as 'peer review', 'quality assurance', 'quality improvement', 'quality activities', 'quality studies', and 'audit' are often used synonymously and are considered components of a Quality Assurance programme.

It's common for a Human Research Ethics Committee (HREC) to be confronted with a project that is unambiguously a Quality Assurance (QA) project. Nevertheless, even if an ethical opinion is sought, a QA project does not necessitate HREC approval. These projects should be registered as per the Hospital and Health Service (HHS) Clinical Governance process. For further details regarding requirements, do consult your local Clinical Governance officer.

Clinical Governance, being a prerequisite of the compulsory National Safety and Quality Health Service Standards and the related Australian Health Service and Quality Accreditation (AHSSQA) scheme, is required for these activities. For additional details, please refer to the list of web links in the beginning of this document.

It's important to note that these activities demand Clinical Governance approval, not Research Governance authorisation. The National Health and Medical Research Council (NHMRC) has published a guidance document concerning ethical considerations in quality activities. For this, see the list of the list of web links in this document and refer to the section on Ethical Considerations in Quality Assurance and Evaluation.

In situations of uncertainty, the HREC Administrator for the ethics committee corresponding to the institution implementing the project can provide further guidance.

4.2 Prior to Commencement

Before preparing your application, it's advisable for researchers to review the following policy documents:

Queensland Health Research Management Policy (RMP).

Research Ethics and Governance Directive

These documents outline the Research Management Framework for all research activities conducted within or in collaboration with Queensland Health. They align with the National Health and Medical Research Council (NHMRC) National Statement on Ethical Conduct in Human Research (2007) (Updated 2018) (The National Statement), the NHMRC and Universities Australia Australian Code for the Responsible Conduct of Research (2007) (The 2018 Code), and relevant State legislation and regulations.

4.3 The Ethics Application

The HREC Application Form (HREA)

All applications for a Human Research Ethics Committee (HREC) review of research must be completed on the Human Research Ethics Application form (HREA), regardless of the level of risk (i.e., Low and Negligible Risk (LNR) research must be submitted using the HREA).

The HREA is available from the Ethics Review Manager (ERM) forms website or the NHMRC website. You can find the links at the beginning of this document referring to either the ERM Application forms or the NHMRC HREA.

Both versions of the form will be accepted for an HREC review as they are the same form, available from different IT platforms. However, all applications for review by a Queensland Health HREC must be submitted via the ERM website. You must register on the site before you can access the forms. Guidance for accessing and navigating the forms is available under the Help tab on the website.

If the NHMRC version of the HREA has been completed, it can be transferred into ERM using the following process:

- Save the NHMRC HREA as an XML file.
- Log into ERM and import the form using the Import Xml icon in the ERM Action Tiles to complete the import of the XML file.
- All supporting documents must be uploaded into the ERM HREA for submission.

The HREA has been designed to meet the requirements of the NHMRC “National Statement on Ethical Conduct in Human Research” (2007) (updated 2018). The National Statement requests the researcher to respond to the fundamental ethical principles and considerations for HRECs and researchers in determining the ethical acceptability of a research study.

While preparing your application, refer to the National Statement as it will answer any queries you have about what an HREC will be looking for from the responses you provide. Information icons and prompts throughout the HREA will provide additional guidance.

The HREA builds a customised ethics application form according to the type of research study by disabling questions and sections that are not relevant. Thus, you will only see questions pertinent to your research proposal. Responses to questions in the HREA should

refer reviewers to the relevant section of the protocol or other supporting documents. Detailed responses in the HREA are only required if the question has not been covered in the project documentation.

Please note that the HREA is merely an application form. It is not a study plan or protocol.

4.4 The Study Plan or Protocol

A study plan or protocol is mandatory for all applications – it is the living document for the project and provides the background and justification for the project, details the research aims, hypothesis (if applicable), methodology, risk management including data protection, and statistical analysis. The protocol should be written in such detail that if the principal researcher is unable to complete the project, another researcher can continue the work using the protocol.

The institution in which you are based may have its own preferred protocol template – consult with the HREC Administrator if uncertain. Queensland Health provides a protocol template on its website, which is written for a clinical trial, but which may be modified to fit any type of research project. Please see the list of web links the list of web links in the beginning of this document and refer to the Protocol Template.

All protocols must have a version number and date. If changes are made to the content of the protocol, both the version number and date should be updated to distinguish one version from the next.

The protocol may not be changed without submitting the proposed changes (i.e., protocol amendments) to the HREC for approval. HREC approval (and subsequent research governance authorisation, if applicable) must be obtained prior to implementing the change to the research. This includes notification to the HREC of any administrative changes (e.g., correction of typos).

The only exception to this is where participant safety is directly threatened if immediate protocol changes are not implemented. All supporting documentation must be uploaded into the HREA and submitted via ERM. Each document should have version details included in the cover page or footers.

4.5 Supporting Documentation

All supporting documentation must be uploaded into the HREA and submitted via ERM. Each document should have version details included in the cover page or footers.

For single site research, all documents should be submitted for ethics review, except for site-specific documentation required for research governance assessment, e.g., study budgets, contracts, and letters of support from relevant Heads of Departments. All documents created specifically for the project must have footers with identifying version details.

For multi-site research, submit the same documents as for single-site research, except where site-specific changes will be made to documents (e.g., Participant Information Consent Forms or fliers). In these cases, a Master version of the document should be submitted, with site-specific details left blank.

If a document is a Master version, on which a site-specific version will be based, this should be reflected in the footer. Please see the Researcher Tip below.

Please be aware that for multi-site research, unless otherwise agreed by each Research Governance Office (RGO), a site-specific assessment form must be created for each participating site. This includes sites that may be in jurisdictions that use a different software system for creating and processing research applications. For sites that do not use ERM, a Minimum Data Form (MDF) may be required to allow the creation of the site-specific assessment form. Each different software system will require its own MDF.

5 Consent

All research which involves participants, or information (including biological samples) must have consent (or permission) for participation or for the use of the information – unless:

- the HREC has granted a Waiver of Consent, in accordance with the National Statement s2.3.9

AND

- the researcher can identify a lawful authority for the use of the information.

The basic principles of consent are that it should be a voluntary choice, based on sufficient information and adequate understanding of both the proposed research project and the implications of participating *(National Statement s2.2.1)*, and the person must have capacity to consent.

Consent may be expressed orally, in writing, or by some other means (e.g., return of a survey). Considerations for choosing the type of consent to be used include the nature, complexity, level of risk of the research and the participant's personal and cultural circumstances. *(National Statement s2.2.5).* Consent for participation in clinical trials should be in writing.

The use of digital technology to support the consent process is becoming more popular. It does not remove the requirement for a consent form but is used as a tool to facilitate information about the project. Further information is provided in section 2.4.11 below.

A researcher may sometimes request, in their HREC application or research protocol, a *Waiver of Consent* where it is impracticable to obtain consent from every individual whose information will be used. Please see section 2.4.9 for further information. Please also note that a *Waiver of Consent* from an HREC does not replace State or Commonwealth legislative requirements regarding the use of personal information.

The *National Statement* chapters 2.2-2.3 discusses consent options for research projects.

Researcher Tip: Writing Consent forms. Generally, all documentation that is given to participants should be written for a 12-year-old reader level – or younger, depending on the participants. Consider the language that is used and the various cultural backgrounds of the target demographic. Some PICF templates are very long and may be repetitive. Do not repeat information in the PICF. Try not to make them too long. Researchers wishing to evaluate their participant information for readability may wish to use a tool such as the Gunning Fog Readability index. Go to the list of web links in this document and refer to Gunning Fog.

Queensland Health HRECs prefer that the Information Sheet, Consent form and Withdrawal of Consent are presented as one document, so that the footer details are constant throughout.

5.1 Participant Consent

If consent is being obtained from project participants, template Participant Information Sheets and Consent forms (PICFs) are available on the NHMRC website. It is not compulsory to use these templates, but it is advisable to use them. For researchers who wish to develop their own PICFs, these templates should be used as a guide in developing their own forms, bearing in mind the language of the HNMRC template can be changed to suit the study and target participant groups.

Please see the list of the list of web links the list of web links in the beginning this document and refer to NHMRC PICF Templates (scroll to Additional Resources).

The Consent Documents

The consent documents generally consist of three parts: an Information Sheet, the Consent form and a Withdrawal of Consent (if applicable). The three parts (or at least the first two, if a *Withdrawal* is not being provided) must be collated into one document. The version details on the *Consent* must be the same as the version details on the *Information Sheet* so that it is clear which version of the Information Sheet the participant has been consented to. Additionally, if a *Withdrawal of Consent* is to be used, it must be added to the suite of information and consent documents with the same version details in the footer.

If, during a research project, the Information Sheet is amended, all active participants must be re-consented to the new Information Sheet and Consent form after HREC approval (and RGO authorisation) has been obtained for the amendment.

If there are pertinent facts in the Information Sheet – such as disclosure of identifiable information outside Queensland Health, or additional exposure to ionising radiation – these should be included as additional dot points on the Consent form so that it is clear that participants are aware of these items.

5.2 Consent for Adults with Impaired Capacity

If the research proposal involves participants who may, by reason of physical and/or mental incapacity, be incapable of giving informed consent to participate in the research, consent may be provided by the legally authorised representative. The type of research will determine which legislation the legally authorised representative will be identified under.

The Queensland Civil and Administrative Tribunal (QCAT) operates under the legislative requirements of the *Guardianship and Administration Act 2000 (Qld)*. On receipt of an application, QCAT will review relevant medical research and, according to the type of project, can provide approval for consent to participate in research to be obtained from a proxy – either from QCAT itself, or from a legally authorised representative.

Most clinical drug or device trials fall within this category. However, as per Sc 2(13)(1A) of the *Guardianship and Administration Act*, a comparative assessment of health care already proven to be beneficial is not considered medical research and does not require review by QCAT.

For other research that does not require review by QCAT, the *Powers of Attorney Act (Qld) 1998 (Ch 4)* provides the legal permission for a Statutory Heath Attorney to give consent for participation in research on behalf of another person who does not have capacity to consent.

The QCAT Process:

QCAT review and approval will result in one of two outcomes – consent to be obtained on a case-by-case basis from QCAT, or approval for consent to be obtained from the legally authorised representative. This decision is based on the type of project.

Approved Clinical Research (See the *Guardianship and Administration Act*, Sc 2(13)).

Research that falls within this definition includes trials of drugs (Phase II or Phase III only) or techniques involving the carrying out of health care that may include the giving of placebos to some of the participants in the trial; or other medical research intended to diagnose, maintain or treat a condition affecting the participants in the research. Because of this, it is categorised as a *Health Matter* under the Act, rather than *Special medical research or experimental health care.*

Approval from an HREC is required prior to submitting an application to QCAT. **QCAT Form 16** is used and all relevant supporting documentation for the project, including the HREC approval letter, must be provided to QCAT. Please see the list of the list of web links the list of web links in the beginning of this document and refer to *QCAT*. (Click on *Resources,* then *Forms)*

QCAT review time takes approximately 4 weeks and will cover all Queensland Health sites named in the application. Approval from QCAT is for the project itself, rather than for an individual's participation. Once QCAT approval has been obtained, the legally authorised representative may consent to a person's participation in the clinical trial or research.

With QCAT approval, disclosure of confidential information is covered by s150A of the *Hospital and Health Boards Act.* **A *Public Health Act* approval is not required.**

Special Medical Research or Experimental Health Care (See the *Guardianship and Administration Act*, Sc 2(12).

Research that falls within this definition includes medical research or experimental health care relating to a condition the adult has or to which the adult has a significant risk of being

exposed; or medical research or experimental health care intended to gain knowledge that can be used in the diagnosis, maintenance or treatment of a condition the adult has or has had. Phase I clinical trials may be included in this category because they are not proven to be effective at treating a condition.

Participation in this type of research must be approved by QCAT on a case-by-case basis. The legally authorised representative cannot provide consent. QCAT will provide the consent for each specific individual.

For projects defined as *Special Medical Research,* use QCAT Form 13

For projects defined as *Experimental Health* Care, use QCAT Form 14

Please see the list of the list of web links the list of web links in the beginning of this document and refer to *QCAT*. (Click on *Resources,* then *Forms)*

The application to QCAT is made after HREC approval and prior to research governance. Review time takes approximately 4 weeks. However, in urgent cases, QCAT may be contacted for prioritised reviews.

Powers of Attorney Act

For other research projects not mentioned above, consent may be obtained from the Statutory Health Attorney under the *Powers of Attorney Act (Qld) 1998 (Ch 4).* There is no application form for this, and no formal permission is required. It is the legislative permission that allows a statutory heath attorney to provide consent to participate in research.

If the mental incapacity is temporary or episodic, an attempt should be made to consent the participant at a later time, when their condition does not interfere with their capacity to make an informed decision about ongoing participation *(National Statement s4.5.6).* In this case, A *Consent to Continue* may be appropriate.

5.3 Witness to consent

A witness to a consent is not required except as indicated in ICH GCP 4.8.9, as follows:

If a subject is unable to read or if a legally acceptable representative is unable to read, an impartial witness should be present during the entire informed consent discussion. After the written informed consent form and any other written information to be provided to subjects, is read and explained to the subject or the subject's legally acceptable representative, and after the subject or the subject's legally acceptable representative has orally consented to the subject's participation in the trial and, if capable of doing so, has signed and personally dated the informed consent form, the witness should sign and personally date the consent form. By signing the consent form, the witness attests that the information in the consent form and any other written information was accurately explained to, and apparently understood by, the subject or the subject's legally acceptable representative, and that informed consent was freely given by the subject or the subject's legally acceptable representative.

If the study only recruits participants who are competent to provide their own consent, the witness statement may be removed from the document.

However, when using a verbal consent process (see below), a witness to the consent process is advised.

5.4 Verbal Consent

There are limited circumstances in research where verbal consent is acceptable, and the *National Statement* provides general guidance on this.

Clinical Trials:

In clinical trials of drugs or devices, a verbal consent process may be approved by the HREC if the clinical trial is conducted under emergency conditions where recruitment is opportunistic, there are tight time limits for administration of interventions, and the intended participant is not able to provide written consent to participate (e.g. acute stroke, cardiac arrest or acute trauma) (see *National Statement* ch 4.4). In those emergency instances, verbal consent from the participant (or legally authorised representative - if they are not yet "on site") may be approved.

Researchers should develop an oral/telephone script to ensure all relevant information is provided, and this should be approved by the Reviewing HREC. A person independent of the research team should witness the entire conversation and an entry documenting the consent process must be made in the medical notes.

QCAT approval for the trial must also be obtained if it is anticipated that participation in the trial relies on consent from the legally authorised representative. Where verbal consent has been obtained from the legally authorised representative, written consent (or *Consent to Continue)* from the legally authorised representative should be obtained as soon as possible.

When the participant has capacity to understand and make an informed decision about whether to continue their participation, a *Consent to Continue* form should be signed.

Non-Clinical Trials

Other situations where verbal consent may be approved is when contacting patients to obtain consent to use medical information in a publication.

However, written consent is always the preferred form of consent and in Queensland Health, verbal consent will only be accepted for research purposes if the HREC has approved the verbal consent process in the context of the individual, specific research protocol.

An institution may choose to not accept an HREC approved verbal consent process if it does not align with the risk profile for the institution.

5.5 Deferred (delayed) Consent

The term *Deferred Consent* (or delayed consent) is not recognised by Queensland Health and does not exist in the *National Statement*. Deferred consent is not a legally recognised form of consent as it is not possible to obtain consent for something after it has already happened. Accordingly, the concepts of deferred or delayed consent are not recognised or supported by Queensland Health, and Queensland Health requires that the terms must not be used by researchers or Queensland Health HRECs.

5.6 Consent to Continue

If consent cannot be obtained from the individual or their legally authorised representative, generally they cannot participate in a research project. The exception to this is emergency situations, where a clinician wishes to conduct a clinical trial that compares two or more interventions which, in general use, would be considered to have equal benefit and risk. The *National Statement* ch 4.4 provides additional guidance on this (see also *Verbal Consent* above).

Later, when the participant has regained their capacity to consider ongoing participation, or when a legally authorised representative is available to provide written consent for the participants ongoing involvement, *consent to continue* in the research is appropriate.

The process to be used in this instance is as follows:

Ethics approval of the entire recruitment, consenting and consent to continue process.

QCAT approval of the clinical trial

5.7 Consent from Minors

The age at which a person becomes an adult in Australia is 18 years. Although young people aged 16 years or older can give legal consent to medical treatment, they usually cannot give legal consent to participate in research until the age of 18 years. Some HRECs may approval mature young people under 18 years to give their consent for certain kinds of research. For participation in all research projects, mature minors should be provided with an information sheet about the study and included in the discussion about participating.

Some consent forms may include an *Assent* statement to be signed by the child, when asking their agreement to take part in a clinical trial or other research. Assent should be obtained with the child is considered to have sufficient maturity to be able to express a view on whether they would like to participate. (Ref NHMRC *Australian Clinical Trials Handbook*)

5.8 Waiver of Consent

In low-risk projects, (e.g., those using data or stored tissue only, or some observational studies), it may not be possible or practicable to obtain consent from every person whose data will be used. In these cases, the HREC may grant a Waiver of Consent.

The HREA contains a question relating to a waiver of consent – but the question may not appear, depending on how previous questions are answered. Therefore, researchers who are requesting that consent is waived should comment on this in their protocol or study plan (Consent section) and justify the request using the reasons in s2.3.10 of the *National Statement*.

The *National Statement* s2.3.9 – 2.3.11 provides additional information about waiving consent.

2.4.1 Implied consent

Implied consent is when a person's actions indicate their agreement (or not) to participate in an activity. In some low-risk research projects, consent is implied if a respondent completes a task related to the project, such as completing a survey.

If this form of consent is to be used, the project must be of low or negligible risk, and information should be provided to the potential participant to allow them to make an informed decision whether to participate.

For example, a survey should have an introduction or preamble that:

- describes the project,
- introduces the researchers.
- provides information on whether responses are anonymised.
- state the measures are in place to protect the privacy of responders and their answers.
- contains a statement saying that completion and return of the survey indicates consent to be involved.
- Additionally, if the survey is conducted electronically and the server is hosted outside Australia (e.g. survey monkey) the potential respondent should be informed about this in the preamble.

> Researcher Tip: Suggested wording when a server is outside Australia.
>
> The survey is being conducted using [name of survey tool] which is based in the [name of country]. Information you provide on this survey will be transferred to [name of survey tool]'s server in the [name of country]. By completing this survey, you agree to this transfer.

The whole survey, including the introduction or preamble, must be approved by the HREC.

5.9 Opt-Out Approach

The opt-out approach is a method used in the recruitment of participants into research where information is provided to the potential participant regarding the research and their involvement, and where their participation is presumed - unless they take action to decline to participate (National Statement, Ch 2.3). However, an opt-out approach has specific requirements relating to its use, and there are relatively few situations where this would be approved by an HREC.

An information sheet about the project is to be provided to each intended participant. The researcher must ensure that the intended participants read and comprehend the information sheet and understand how they can opt out of participation.

An opt-out approach is not consent. In fact, it is an absence of consent. This means that in situations where consent is required or is being relied upon as a legal permission, an opt-out approach cannot be used.

Researcher Tip: An absence of an opt-out notification does not indicate agreement to participate. If the Information Sheet is not being provided directly to intended participants (i.e. it is being posted, or sent by email), the researcher must consider whether the absence of an opt-out notification is because the intended participant has not received the information, has not yet returned the opt out form, or does not have access to the internet at that time. An absence of an opt-out notification does not indicate agreement to be involved.

If an opt-out approach is used (for example, to provide information to a registry), the researcher must request a Waiver of Consent from the HREC, and a *Public Health Act (PHA)* grant may be required to allow the lawful disclosure of identifiable or potentially re-identifiable information without the consent of the person to whom the information relates, if the information will be disclosed outside Queensland Health.

If the information to be disclosed is not identifiable or potentially re-identifiable, a PHA may not be required. Check with the HREC Administrator if uncertain.

5.10 e-Consent

e-Consent involves the use of electronic media to support the delivery of information to potential research participants. Currently, a standard consent process involves provision of hardcopy documentation, sometimes of considerable length, to a potential participant, or their legally authorised representative. However, not all people have the same literacy levels and with clinical trials becoming increasingly complex, alternative means of imparting relevant information about the research have been developed.

e-Consent tools may include videos, diagrams, and other digital components. These should not replace the discussion that occurs between the potential participant and the investigator, but they do have the potential to enhance understanding of the research project.

Written consent is still required unless another form of indicating consent has been approved, such as the completion and return of a survey.

All e-Consent tools must be approved by the HREC prior to their use.

5.11 Dynamic Consent

Dynamic consent is a flexible and user-friendly approach to consent that allows individuals to make informed decisions about their participation in research projects. Unlike traditional consent, which is usually a one-time agreement given at the start of a research project, dynamic consent allows participants to adjust their consent choices over time as the research progresses.

This means that participants can choose to opt in or out of different parts of the research, or withdraw their consent entirely, at any time. They can also update their personal information and preferences as needed. This approach is often facilitated through digital platforms, making it easier for participants to stay informed and engaged with the research.

In essence, dynamic consent is about giving participants more control and flexibility over their involvement in research, promoting transparency and trust between researchers and participants.

5.12 Consent to Approach (for research)

Sometimes a researcher external to Queensland Health may negotiate to enter a clinical environment to undertake research involving patients, and which requires Queensland Health staff to identify (in real time) patients to approach as potential participants.

Queensland Health staff may not disclose information (including the patient's name) to the researcher without permission.

Therefore, a *Consent to be Approached for Research* form should be developed (and submitted for HREC Approval), for Queensland Health clinicians to give to selected patients. The form does not need to be lengthy (ideally less than one page including signatures) but should contain the following information:

- Project title and HREC reference number
- A summary (1 paragraph) of what the project is about.
- A description of who is carrying out the research.
- A simple consent to be approached. For example: I give permission for XXX from XXX to speak to me about this study Yes / No
- An additional statement providing clarification around what the consent to be approached means. For example: *Giving permission to be approached does not mean that I will agree to participate, only that I agree for XXXX to provide me with further information about the study.*
- A section for the patient to sign the Consent to be Approached.
- The form should be filed in the patient's medical record and the information passed to the external researcher. If the patient consents to being approached, the external researcher may then be provided with the patient's name and may approach the patient to talk about the project.
- Signing the *Consent to be Approached* does not negate the requirement for consent to participate if the patient agrees to be involved.

6 Clinical Trials

Definition

The World Health Organisation (WHO) definition for a clinical trial is any research study that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes. Clinical trials might also compare existing interventions, test new ways to use or combine existing interventions or

observe how people respond to other factors that might affect their health (such as dietary changes).

Clinical trial interventions include but are not restricted to:

- experimental drugs
- cells and other biological products
- vaccines
- medical devices
- surgical and other medical treatments and procedures
- psychotherapeutic and behavioural therapies
- health service changes
- preventive care strategies and
- educational interventions.

Australia has its own regulatory requirements for clinical trials. The Therapeutic Goods Administration (TGA) is responsible for administering the Therapeutic Goods Act 1989. For further information, please go to the Web Links page in this document.

Phases and stages of clinical trials

Clinical trials of medicines and biologicals typically proceed through 'phases' of development whereas clinical trials of medical devices are represented by 'stages'. Trial Sponsors use the objectives of the trial to determine the phase or stage of the trial.

Refer to **Appendix 2** for definitions and explanations of clinical trial phases and stages.

For clinical trials that do not involve medicines/biologicals or devices, (e.g., comparing different types of physiotherapy or education models) there is no need to identify a trial stage or phase. (Ref Therapeutics Goods Administration Australian Clinical Trials Handbook, ver 2.3 Nov 2020).

6.1 Confidentiality Agreements

Researchers will often be asked to sign a Confidentiality Agreement before the Sponsor of a clinical trial or other research project sends detailed information about the study.

The confidentiality agreement must be signed by a representative of the institution, who has the appropriate delegation to sign on behalf of the institution. In most cases, the Principal Investigator does not have this delegation and the confidentiality agreement must be sent to the research governance office for execution.

If a person without the appropriate level of delegation signs a confidentiality agreement, the agreement will not be deemed valid.

6.2 Medical software and mobile medical 'apps'

Medical devices are regulated in Australia by the TGA. Medical software and mobile medical 'apps' used in clinical trials may be regulated as medical devices and therefore may require exemption under the CTN scheme or approval under the CTA scheme. Further information

can be found on the TGA website under Regulation of medical software and mobile medical 'apps'.

A software product is a medical device if it fits the definition of a medical device in section 41BD of the Therapeutic Goods Act 1989. Please see the list of the list of web links the list of web links in the beginning of this document and refer to Therapeutic Goods Act.

Many types of software meet this definition and must be regulated. Some examples of Software as a Medical Device (SaMD) include:

- smart phone apps that calculate insulin doses based on a patient's blood glucose levels.
- X-ray image-processing software
- Software that uses information about a patient to make a diagnosis.

SaMD may be used with or in different computing platforms such as:

- Computers*
- Mobile phones*
- Tablets*

*Note that for the SaMD examples, a mobile phone, computer or tablet is not itself a medical device.

The regulation of medical devices is risk-based according to the level of risk the product represents to the patient or healthcare professional using it. If a research project involves the development and testing of new software, a CTN notification to the TGA may be required. However, for medical device trials, the CTX scheme may be more appropriate where the experimental device introduces new technology, new material or a new treatment concept which has not previously been evaluated in clinical trials in any country.

Health software apps that are not a medical device:

Many mobile apps are simply sources of information, or tools to manage a healthy lifestyle. The TGA does not regulate health and lifestyle apps and software that do not meet the definition of a medical device. (Ref Therapeutics Goods Administration Australian Clinical Trials Handbook, ver 2.3 Nov 2020)

Contact the TGA if uncertain.

Researcher Tip: A ***medical device*** is any instrument, apparatus, appliance, material or other article (whether used alone or in combination, and including the software necessary for its proper application) intended, by the person under whose name it is or is to be supplied, to be used for human beings for the purpose of one or more of the following:

- diagnosis, prevention, monitoring, treatment, or alleviation of disease
- diagnosis, monitoring, treatment, alleviation of or compensation for an injury or disability
- investigation, replacement, or modification of the anatomy or of a physiological process
- control of conception

and that does not achieve its principal intended action in or on the human body by pharmacological, immunological, or metabolic means, but that may be assisted in its function by such means.

6.3 CTN/CTA Schemes

The TGA has established two schemes which provide for the importation into and/or supply in Australia of 'unapproved' therapeutic goods for use in a clinical trial:

- Clinical Trial Notification (CTN) scheme; and
- Clinical Trial Approval (CTA) scheme (please note the new terminology, effective Nov 2020).

Clinical trials that do not involve 'unapproved' therapeutic goods which are being used within their registration limits, are not subject to requirements of the CTN or CTA schemes. However, there is no entry for *placebo* in the *Australian Register of Therapeutic Goods (ARTG)*, thus it is an unregistered therapeutic good and a CTN or CTA must be in place before any clinical trial involving a placebo can commence.

It is the responsibility of the Australian clinical trial sponsor to determine whether a product is considered an 'unapproved' therapeutic good, or whether it is being used “off label”. (Ref TGA website, Regulation Basics, Clinical trials).

The main difference between the CTN and CTA schemes is the level of involvement by the TGA in reviewing data about the therapeutic goods before the clinical trial commences.

The CTN scheme:

The CTN scheme is a notification process, alerting the TGA that unapproved therapeutic goods (or approved therapeutic goods being used for a purpose outside their registration) are being trialed. All sites that are participating in the project should be named on the CTN Form. However, if a clinical trial is being conducted under the teletrials model and there is no investigational product (IP) being stored at the site (i.e., the IP is stored at the primary site and sent to the satellite site when required), it may not need to be listed on the CTN form.

Under the CTN Scheme, the TGA does not review or evaluate any data relating to the clinical trial at the time of submission. All material relating to the proposed trial, including the trial protocol is submitted directly to the HREC. The HREC is responsible for assessing the scientific validity of the trial design, the balance of risk versus harm of the therapeutic good(s) and the overall ethical acceptability of the trial.

The CTN scheme may be used for earlier phase studies if there is adequate preclinical information available, especially regarding safety.

The CTA scheme:

The CTA scheme is an evaluation process and involves the review by the TGA of relevant, but limited, scientific data (which may be preclinical and early clinical data) prior to the start of a trial. This should also be considered for therapeutic goods that are in the early stages of development. The primary responsibility is to review the safety of the product. It is the responsibility of the reviewing HREC to consider the scientific and ethical issues of the proposed trial protocol.

The CTA route is generally for high risk or novel treatments, such as gene therapy, where there is no or limited knowledge of safety, such as Phase I clinical trials and clinical trials of any Class 4 biologicals (although there are some exceptions to this – see the Aust Clinical Trials Handbook ver 2.3, Nov 2020).

It should also be considered for medical devices where the experimental device introduces new technology, new material or a new treatment concept which has not been evaluated previously in clinical trials in any country, or for medical devices that pose a risk of serious patient harm when the HREC does not have, or have access to, adequate expertise in the preclinical technical areas. This is especially relevant for implantable devices where areas of expertise include biological safety evaluation of medical devices, materials quality evaluation, engineering analysis of strength and fatigue of materials, finite element analysis for stress and fatigue prediction, and other computational simulations for device performance.

6.4 Registering a clinical trial on a publicly searchable website.

In 2004 the International Committee of Medical Journals Editors (ICMJE, including editors of the *Medical Journal of Australia, Lancet, New England Journal of Medicine,* and others) declared that they would not consider a trial for publication without evidence that it had been registered in a publicly accessible trials registry prior to enrolment of the first participant.

The Declaration of Helsinki now explicitly states that *every clinical trial must be registered in a publicly accessible database before recruitment of the first subject*, and the World Health Organization (WHO) considers the registration of all interventional trials to be *a scientific, ethical and moral responsibility* (who.int/ictrp/en/).

Registration of clinical trials is not legislated in Australia or New Zealand. However, the *National Statement* s3.1.7 obligates researchers to ensure that their trials are registered in a publicly accessible database:

For any research project that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes, researchers must register the project as a clinical trial on a publicly accessible register complying with international standards (see information on the International Clinical Trials Registry Platform (ICTRP) on the World Health Organisation website) before the recruitment of the first participant.

The trial's sponsor or delegate is responsible for registering a trial. Clinical trials need only be registered once on any Primary Registry in the WHO Registry Network, or an ICMJE approved registry.

Examples of such registries are:

- Australia and New Zealand Clinical Trials Registry (ANZCTR) https://www.anzctr.org.au/Support/AboutUs.aspx
- ClinicalTrials.gov https://www.clinicaltrials.gov
- EU Clinical Trials Register https://www.clinicaltrialsregister.eu

If in doubt about whether to register or not, registration is recommended.

Please note that clinical trials with Australian and New Zealand recruitment sites registered on ClinicalTrials.gov are also displayed on the ANZCTR. (*ref ANZCTR FAQs)*

6.5 What is the Universal Trial Number (UTN)?

The Universal Trial Number (UTN) is a unique identifier allocated to each clinical trial which allows unambiguous identification of clinical trials registered in WHO Primary Registries and displayed on the WHO International Clinical Trials Registry Platform's (ICTRP) Search Portal. It is not a registration number.

A UTN should be obtained early in the development of a clinical trial and should be included in communications and documentation relating to the trial.

For the UTN website, please refer to the list of web links at the beginning of this document.

6.6 Teletrials

Teletrials is an emerging model for the conduct of clinical trials using Tele-health technology to enable a clinical trial to be conducted at a site remote from where the Principal Investigator (PI) is located.

The model consists of a primary research site that engages satellite sites to conduct a clinical trial under the supervision of the PI at the primary site. Collectively, the group is known as a cluster. Satellite sites conduct clinical trial procedures under an agreed, site-specific supervision plan. The level of involvement at each satellite site depends on facilities available and the clinical trials experience of the research staff at the satellite site. A Delegation Log specific to each satellite site, details which tasks will be undertaken at the satellite site and by whom.

A specific Teletrials Subcontract is available on the ORI website (see the list of web links in the beginning of this document and look for Teletrials Subcontract).

Not every clinical trial is suitable to be conducted as a teletrial, but each clinical trial should be evaluated, as soon as possible, as to its suitability to be conducted under this model.

The Sponsor must agree to allow the trial to be conducted under the teletrials model and must also approve each Satellite Site.

The advantage of teletrials is that the model allows potential participants from regional, rural, and remote areas to participate in clinical trials without travelling regularly to the primary site, thus enhancing recruitment potential, and providing equitable access to potential participants in regional, rural and remote areas. Another advantage of this model is that clinical trials units that have not been offered a trial can consider joining a trial as a satellite site.

Regional clinical trials coordinating centres will be established in each jurisdiction to liaise between primary and satellite sites, and Sponsors, and to provide operational support to establish and manage a teletrial.

For further information, contact your local research governance officer or the nearest Queensland Health HREC. Teletrial specific guidance documents are available on the Queensland Health Teletrials website. Refer to the list of web links starting on page 13, and search on (QH) *Teletrials Information.*

6.7 Access to Unapproved Products at the Completion of a Trial

If it is agreed that trial participants can remain on the investigational medicinal product at the completion of the trial, supply of the unapproved products must be lawful and compliant with the *Therapeutic Goods Act.* Access to unapproved therapeutic goods is regulated by the TGA, and there is guidance on the TGA website about accessing unapproved products.

For further information, refer to the list of web links in the beginning of this document and search for *Access to Unapproved Products*.

7 Research sponsor

According to the National Statement, a research sponsor is an individual, company, institution or organisation that takes responsibility for the initiation, management, and/or financing of research.

Every research project has a sponsor - an entity that accepts the risk of the project and responsibility for its conduct - regardless of whether the project is funded.

Researchers commonly assume that the funder of a research project, or an institution administering a research grant, is the Sponsor. For example, if a collaborative research group based within the public health system obtains funding for a research project from the NHMRC, and lodges those funds in a tertiary institution with whom one of the collaborators has an affiliation (but where the tertiary institution has no role in the project except the administration of the grant monies), who is the Sponsor of the project? The Sponsor is the entity that indemnifies the project and the researchers and accepts responsibility for the development of the protocol and conduct of the study – in this instance, most likely the collaborative group.

If uncertain, contact the HREC administrator or local research governance officer for guidance.

8 Student Research

Students undertaking research in Queensland public health institutions while on placement during their training for a health-related profession are considered *Designated Persons* under s139A of the HHB Act and may use Queensland Health information for their research projects if the project can rely on S150 of the HHB Act.

Students who wish to undertake additional research outside their clinical placement (for example during university breaks), cannot be given Queensland Health information without a suitable legislative permission.

Students on placement who are undertaking research that cannot rely on s150 of the HHB Act must identify a permission that allows them to be given information for their project (e.g., Public Health Act).

Students who have already graduated with an undergraduate degree in a health-related profession and who wish to undertake additional training for a higher degree in their health-related profession cannot use Queensland Health information for their higher degree student projects without a suitable legislative permission.

This applies even if the higher degree student is working part-time in Queensland Health in a health-related profession and uses Queensland Health information routinely for their normal clinical work.

All students require an academic supervisor – who may or may not also be their clinical supervisor. If the academic supervisor is external to Queensland Health (or is not a *Designated Person* as defined in s139A of the HHB Act) and will see or be given confidential information from Queensland Health, a *Public Health Act* approval is required.

All students undertaking research in Queensland public health institutions require clinical and academic supervisors. If the student's primary supervisor is not a Queensland public health institution employee, the student should nominate an educational supervisor or Student Liaison Officer from within the Queensland public health system.

If the academic supervisor is external to Queensland Health (or is not a *Designated Person* as defined in s139A of the *HHB Act)* and will see or be given confidential information from Queensland Health, a *Public Health Act* approval is required.

For more detailed advice, please see *Guideline-Disclosure of Confidential Information for Research* on the Queensland Health website.

9 Single site or multi-site research.

Single site Research

If the research project is being conducted in only one site, the project can be reviewed by the local HREC, however the project may be submitted to any NHMRC registered HREC with whom Queensland Health has an agreement. Generally, the site at which potential participants will be recruited from will determine the location of the reviewing HREC. Researchers should liaise with the HREC Administrator as to any specific submission requirements such as hard copies of the application and supporting documents.

Researcher Tip: HRECs that require hard copies of submitted applications. If an HREC requires hard copies of submission documents, the documentation must be sorted into "bundles' so that each bundle contains one copy of each submitted document. Applications that are submitted without documentation being sorted will not be processed.

There is a list of HRECs, their closing and meeting dates and specific site requirements on the ORI website. Please see the list of the list of web links at the beginning of this document and refer to *QH HRECs Information*.

Multi-site Research

For multi-centre research, one investigator must be nominated as the Coordinating Principal Investigator (CPI). The Coordinating Principal Investigator must be employed and professionally based in an Australian organisation. For international studies with a Coordinating Principal Investigator outside Australia, a health professional based in Australia must be nominated as the Coordinating Principal Investigator responsible for the conduct of the research in Australia.

The Coordinating Principal Investigator/or delegate is responsible for correspondence relating to the ethical review in accordance with the *National Statement* chapter 5.2. This function, in part, may be delegated to a person who will act as a contact person on behalf of the Coordinating Principal Investigator.

Each site in which the research will be undertaken should have a Principal Investigator (PI) who accepts responsibility for the conduct of the project at the sites. The CPI must share the HREA with all participating site PIs.

For low-risk projects, the requirement for a PI at the site may be waived in lieu of a site contact person.

Researcher Tip: Sharing the application form with collaborators. In ERM, there are two ways in which the application form can be shared with collaborators: the *Share* option and the *Roles* option. The *Share* option will allow nominated collaborators to see only the form that has been shared, and no other subordinate forms. The *Roles* option will share that form with collaborators, and depending on the permissions given, will also allow them to see all subforms under that form. Queensland Health recommends the use of the *Role* option, rather than the *Share* option.

For sites within Queensland and Victoria that use ERM, the form may be shared online. For sites in States that use other IT platforms for HREC submissions, the HREA should be saved as a .pdf and emailed to the PIs.

Prior to submitting the HREC application, the CPI should consult participating sites about any site specific or jurisdictional specific requirements that should be notified to the HREC.

Supporting documentation that has been specifically created for the study should have version details as outlined in s2.3.3 above.

Researcher Tip: State Specific Modules. Victoria and Western Australia have developed state specific modules which must be completed and submitted for HREC review. Ideally, researchers from within those states should complete their state specific modules and send them to the CPI for inclusion with the HREC application.

10 Forensic and Scientific Services

Research involving access to coronial material must be referred to the Queensland Health Forensic and Scientific Services Human Ethics Committee (FSS-HEC) for ethical and legal approvals. This also applies to clinical research studies 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 autopsies.

The use of material from coronial autopsies for research requires the approval of the State Coroner. If the research involves access to coronial documents approval as a 'genuine researcher' under s53 of the Coroners Act 2003 is also required. These approvals are subject to reviews by an ethics committee whose membership includes representatives of the State Coroner.

Further information is available on the Queensland Health Forensic and Scientific Services website. Please see the list of the list of web links in the beginning of this document and refer to Forensic and Scientific Services Research

11 Research Involving Queensland Corrective Services

All requests to conduct research using Queensland Corrective Services (QCS) participants, facilities or resources must be considered by the internal QCS Research and Evaluation Committee. The Committee functions as an authorising body, regarding all research and evaluation projects involving QCS offenders, staff or records, and generally meets every three months, with additional meetings if necessary.

Approval from a relevant HREC is required prior to submission of a research application to the QCS Research and Evaluation Committee.

Further information is available on the Queensland Corrective Services website. Please see the list of the list of web links in the beginning of this document and refer to *Queensland Corrective Services Research*

12 Research Involving the Department of Education Queensland

The Department of Education, Queensland has developed guidance for research involving Departmental Sites, the recruitment of participants or the use of Departmental, school, staff or student data not already in the public domain.

Applications are processed through Queensland Education Research Inventory (QERI). There is a specific application form available from their website, and minimum processing times for applications is 12 weeks. The nature and the scope of the proposed research determines the level of permission required from the Department. Approval from a relevant HREC is required prior to applying to QERI.

For additional information about undertaking research within the Department of Education, please see the list of the list of web links in the beginning of this document and refer to *Department of Education Research.*
Please note: A Blue Card may be required to undertake research in schools.

13 Research involving Queensland Ambulance Service

If a research project involves personnel or data from Queensland Ambulance Service (QAS), an application must be submitted to the *Information Support, Research and Evaluation Unit* (ISRE) at QAS for review and approval by the Queensland Ambulance Service Research and Innovation Committee (QAS RIC).

If confidential information is sought (identifiable or potentially re-identifiable patient information) approval must also be given by the Director General of Health (or delegate). This process is separate from the *Public Health Act* application. **This includes projects that only use QAS data included in the patient's medical record within an HHS.**

The *Application for Data* form and *Research Application Guidelines* have been published on the QAS website to assist applicants. Please see the list of the list of web links in the beginning of this document and refer to *Queensland Ambulance Service Research and Data Requests.*

Researcher Tip: Queensland Health staff wanting to use QAS Data. Although Queensland Health and Queensland Ambulance Service report to the Minister for Health (Qld), different legislation governs each service. A *Designated Person* under the HHB Act, is NOT a *Designated Person* under the *Ambulance Service Act 1991 (Qld)* and vice versa. A person who is a *designated person* under the HHB Act must abide by the privacy provisions in the *Ambulance Service Act*, even when the ambulance data is held within the Queensland Health medical record.

The suggested process is as follows:

Early discussion with QAS Data Custodian, while developing the research protocol or plan to ensure the required data is available.

- Obtain HREC approval to ensure no changes to data required.
- Apply to QAS using the *Application for Data* form. **Please note** responses may be copied directly into the form from the HREA or protocol.
- When approval from the Director General (or delegate) and the QAS RIC has been granted, and relevant research governance authorisation obtained where required, the data will be provided to the researcher.

For further information or to contact the QAS ISRE prior to commencing a project, use the contact details on the QAS Research website.

14 Research Involving Ionising Radiation

In cases where a research project involves the use of ionising radiation exceeding the standard amount a patient would typically receive, it is mandatory to procure a report detailing the radiation dose and risk assessment for each distinct machine to be used at every site. This report should also include information about the amount of radiation the participant will receive because of their involvement in the research project. This information should be included in the Participant Information and Consent Form (PICF).

The Australian Radiation Protection and Nuclear Safety Agency (ARPANSA) is the country's leading authority on radiation protection and nuclear safety. It is tasked with ensuring compliance with the Australian Radiation Protection and Nuclear Safety Act of 1998 and developing Australia's radiation protection standards. According to the ARPANSA Code of Practice for the Exposure of Humans to Ionizing Radiation for Research Purposes (2005) RPS8, human research studies that involve imaging must have a radiation dose and risk assessment report prepared by a qualified medical physicist.

For arranging a report for sites under Queensland Health, please contact Biomedical Technology Services (BTS). It is necessary to have an individual report for each machine because, in multi-site research, machines at different sites may vary in age, manufacturer, and software. This requirement is stipulated in RPS8 Annex 3 (a).

For further information and resources, please refer to the list of web links provided at the beginning of this document and consult ARPANSA's website.

15 Clinical Registries

Clinical registries are databases set up to collect clinical information on patients with a specific condition. They should have a formal structure and management process in place, including rules for collection, storage, disclosure, and protection of the information they hold. Depending on the type of registry, HREC approval may not be required, but it is recommended.

There are different types of registries, for example:

Clinical Disease Registries: The purpose of these registries is to collect clinical information on patients with specific disease or conditions that are the subject of the registry.

HREC approval should be obtained for this type of registry.

Clinical Quality Registries: An organisation which systematically monitors the quality (appropriateness and effectiveness) of health care, within specific clinical domains, by routinely collecting, analysing, and reporting health-related information. The information is used to identify outcome benchmarks, significant outcome variance, and inform improvements in healthcare quality.

HREC approval is not necessary for this type of registry, but institutional review and oversight is required, for example, oversight by the institution's quality improvement service. (Ref: Australian Commission on Safety and Quality in Health Care: Framework for Australia clinical quality registries)

Clinical Registries established for the purposes of research: According to the National Statement, clinical registries which are established for the purpose of research are databanks, and those researchers wishing to establish a databank should be familiar with the requirements of the relevant sections of the National Statement.

HREC approval is required.

Drug or Device Registries: These registries may be set up after completion of pre-registration clinical trials, to provide long term monitoring of the safety and efficacy of drugs and devices.

HREC approval is required.

Information from registries is generally provided back to clinicians to inform clinical practice and decision making.

Researchers who wish to set up a registry should take the following steps:

- establish the purpose and scope of the registry.
- identify stakeholders who would contribute to, and benefit from, the registry.
- evaluate its feasibility, including ease of data acquisition, estimated size, extent of data collection, management, and security of data.
- identify what tool or software will be used for the registry and where the server is located.
- nominate the form of consent that will be used to acquire the data.
- build a registry team to oversee the registry.

- establish the rules and governance of the registry.
- determine the regulatory and ethical requirements, including for the use and disclosure of data.
- develop a study plan or protocol, including any supporting documentation based on the items above.
- develop a project plan.

Additional guidance for the establishment of a registry can be obtained from the following sources:

The National Statement Chapter 3, Element 4

The Australian Commission on Safety and Quality in Health Care has developed guidance documents, including strategic principles, for the establishment and operation of registries. Please see the list of the list of web links in the beginning of this document and refer to The Australian Commission on Safety and Quality in Health Care (click on Publications and Resources, and search for Registries).

The NHMRC has published additional guidance: Ethical Considerations in Quality Assurance and Evaluation Activities. Please see the list of the list of web links in beginning of this document and refer to Ethical Considerations in Quality Assurance and Evaluation Activities.

16 Choosing a Human Research Ethics Committee (HREC)

In Australia, HRECs review research proposals that involve human participants to ensure that they meet ethical standards and guidelines. These guidelines include the National Statement, which requires many types of human research to undergo ethics review. It also sets out the requirements for an HREC's establishment, operation, and membership.

In accordance with the National Statement, Ch 5.3, Queensland Health supports minimisation of duplication of ethics review.

All Australian State and Territory Departments of Health have signed a Memorandum of Understanding (MOU) for mutual acceptance of the ethics review conducted by an NHMRC Certified HREC within the public health system.

This means that for multi-centre human research being conducted within the public health systems in Australia, generally only one HREC review is required. However, there are some exceptions to this, and they are listed below.

Multi-centre research projects that are exempt from single ethics review under NMA are as follows:

- Projects involving persons in custody or staff of the jurisdictional Justice Health departments.
- Projects specifically affecting the health and wellbeing of Aboriginal and Torres Strait Islander people and communities.

- Projects involving access to coronial material.
- First Time in Human or Patient (FTIH/FTIP) and Phase 1 clinical trials (in NSW, ACT, NT and SA only).

For these projects, HREC review must be undertaken in each State, according to jurisdictional guidelines.

The MOU signed by the Departments of Health in Australian States and Territories does not include HREC review by certified HRECs outside the public health system (e.g., tertiary institution HRECs or private HRECs).

16.1 Certified HRECs

For a single ethics review process to be accepted, the NHMRC introduced an assessment scheme to evaluate the processes of HRECs that nominated to participate in the scheme. HRECs whose processes were accepted by the NHMRC are called certified HRECs and the reviews from these certified HRECs which are based within the public health system are accepted across the public health organisations.

All HRECs that are certified for multi-site ethics review must have also firstly been registered with the NHMRC.

Additional information about National Mutual Acceptance may be found on ORI's website. Please see the list of the list of web links in this document and refer to National Mutual Acceptance.

The NHMRC publishes a list of certified HRECs. Please see the list of the list of web links in the beginning of this document and refer to NHMRC Certified HRECs.

Please note: Queensland Health institutions do not accept the ethics review from every certified HREC. The institution supporting the certified HREC must have an agreement with Queensland Health to engage in mutual acceptance of ethics review. Please check with the local HREA administrator or research governance officer if uncertain.

16.2 Registered HRECs

The NHMRC publishes a list all HRECs that nave notified the NHMRC of their existence, and who declare that the HREC meets the requirement of the National Statement.

Additionally, the NHMRC requires that organisations that receive its funding must conduct human research in accordance with the National Statement.

Over 200 HRECs in organisations across Australia are registered with the NHMRC.

The NHMRC publishes a list of Registered HRECs. Please see the list of the list of web links in the beginning of this document and refer to NHMRC Registered HRECs.

16.3 Choosing an HREC to review research applications.

The HREA asks questions relating to the type of research project, and whether it is a single site or multi-centre study. The responses to these questions will determine the which ethics committees are offered in the drop-down list of HRECs that appears in the HREA. Researchers can select their preferred HREC from the drop-down list and submit their study on-line for review.

For contact information and information about site submission requirements, closing dates and meeting dates of Queensland Health HRECs, please see the list of the list of web links in the beginning this document and refer to QH HRECs Information.

16.4 Inclusion of Private Sites in an HREC Review.

Sites to be covered by an HREC review must be listed in the application. If there are private institutions listed, the following points must be considered before liaising with the HREC Administrator to discuss whether the private sites will be covered by the HREC review:

- does the private institution have its own HREC and has it reviewed this project?
- will the private institution accept the review of a Queensland Health HREC?
- is there an agreement in place between the Queensland Health HREC and the private institution to allow HREC monitoring of the project in the private institution, including potential access to patient data?
- if commercially sponsored research, has the private institution been listed on the Form of Indemnity?
- If investigator-initiated research, has the private institution offered indemnity to the Queensland Health and HHS HREC?

17 Queensland Health Information for Research

Many people wish to use Queensland Health information for research projects. However, Queensland Health has strict legislation and polices regarding access to, disclosure and use of the information it holds. A patient's medical record contains personal and private information which must be respected and protected by those who use it.

17.1 Please refer to Guideline-Disclosure of Confidential Information for Research on the Queensland Health website.

18 Amendments to Approved Research

Any changes to the research protocol or supporting document must be approved by the HREC prior to being implemented. ERM has a specific form, created as a sub-form of the HREA, on which amendments may be submitted.

Version details of all amended documents must be updated, to provide version control, and all amended documentation must be uploaded into the form, for submission. When HREC approval or acknowledgement of the amendment has been received, the amendment should be submitted to the RGO at each participating HHS for site authorisation.

The **ONLY** exception to this is if patient safety is directly affected. If this is the case, the change must be notified to the HREC and the research sponsor as soon as possible.

19 Reporting Requirements

The HREC Approval letter will outline reporting requirements specific to each research project. HREC Approval may be contingent upon submission of Annual Reports and any other reporting requested by the HREC. Researchers who are non-compliant with reporting risk having their ethics approval revoked.

For multi-site research, the CPI should collate all Annual Reports from the sites for which they are CPI and submit these as required to the HREC. When the HREC acknowledgement has been received, it should be provided to the participating sites.

Safety reporting in clinical trials is in accordance with the *Safety monitoring and reporting in clinical trials involving therapeutic goods* guidance published by the NHMRC. See the list of the list of web links at the beginning of this document and scroll to the NHMRC section.

For any other reporting requirements, contact the HREC administrator if uncertain which form to use or how to proceed.

20 Research Governance Applications

The Research Governance Office/r (RGO) is responsible for assessing site-specific aspects of research applications, making a recommendation to the Hospital and Health Service Chief Executive (HHS CE) (or delegate) as to whether a research study should be authorised at that site, and overseeing that authorised research at the site meets the appropriate standards.

The site-specific assessment considers the following matters:

- resources (financial, human, equipment, and infrastructure) required for the research to proceed at the site and identified as appropriate, accountable, and available.
- researchers have the necessary expertise and experience; if not, relevant training is planned before carrying out their role in the research study.
- compliance with relevant laws, policies and codes of conduct relating to matters such as privacy, confidentiality, consent, biosafety, professional standards, and radiation safety.
- A letter of authorisation to conduct research will be issued to the applicant usually within 25 calendar days from submission. The HHS CE (or delegate) retains responsibility for authorising the conduct of research at the site.

Final Queensland Health institutional authorisation will be contingent on:

- HREC approval of protocol

- completed Site Specific Assessment (SSA) Form (unless this requirement has been waived by the RGO)

and where required:

- approval to access confidential health information for the purposes of research under the Public Health Act (Qld)
- approval from QCAT for research involving adults with impaired capacity to consent.
- approval from Pathology Queensland to access tissue samples held by Queensland Health
- approval from the Queensland Health Forensic and Scientific Services Human Ethics Committee, where studies involve material from coroners' autopsies.
- approval from any other committee or organisation that is required for the research to be undertaken.
- Research governance must be undertaken for each participating site. Negotiations pertaining to the research governance processes (HHS & Legislative requirements as documented on the SSA Form) should commence and run parallel to the HREC approval cycle.

Commencement of the research within an HHS can only occur after HHS Authorisation has been provided. HREC approval alone is not authorisation to conduct the research.

Research Governance Application form

An SSA form documents all aspects of research governance arrangements for a study at a particular Queensland Health site. It may be submitted at any time but will not be validated for formal review until **after** HREC approval is granted - in case the ethics review requires modification to the protocol or supporting documents.

The Site-Specific Assessment form (SSA)

The SSA form is used for research governance processing. It is created as a subform of the HREA (or MDF when HREC review has not been undertaken in Queensland Health or Victoria Health) and is only available from the ERM website. The SSA form does not exist in the NHMRC website.

> Researcher Tip: How to Create an SSA Form when the HREA was not created in ERM
>
> If the HREC review was undertaken in a jurisdiction that does not use ERM, there will be no HREA in ERM from which to create the SSA. Therefore a "fake" ethics application must be created in ERM to allow an SSA form to be created. The form to use is the Minimum Data Form (MDF). Further information is provided below.

An SSA form must be completed for each separate Hospital and Health Service (HHS) that is participating in the research project – unless the relevant RGO has waived the requirement to complete an SSA form. The SSA form must be signed by the Principal Investigator (PI) before it can be submitted. Signatures may be:

- wet ink, on the printed signature page of the SSA form and then uploaded against the signature placeholder.
- electronic – by sending a request through ERM to the PI, requesting an electronic signature (the PI must have an account in ERM to perform this method of signing)
- a letter on institutional letterhead or email from a professional email account may be accepted and uploaded (e.g., the email cannot come from a personal email such as *Bloggsfamily@bluebells.com).*

20.1 The Minimum Data Form (MDF)

The SSA form is only available as a sub-form of the ethics application (HREA). If the HREA was not created in ERM, an alternative "parent form" for the SSA must be used. The Minimum Data Form (MDF) has been developed to collect the minimum data required to create a "virtual" ethics application so that an SSA form can be created as a sub-form in ERM.

In ERM, only one MDF is required for all SSAs for the same project - provided that the person who creates the MDF gives all intended users of the MDF a Role in the project. This allows all users to create their own SSAs from the same "parent" form.

Documents that are uploaded in the MDF will not automatically transfer to the SSA Form – so all uploaded documentation in the MDF must be downloaded and saved, then uploaded into the MDF. The advantage of uploading documents against the MDF is that all users will have access to the same documents from the same source.

> Researcher Tip: Downloading all documents from an ERM application together.
>
> Documents may be downloaded from ERM individually (time consuming) or all together at the same time. To download all documents at the same time, select the project and open the application form which has the documents uploaded in it. In the Action Tiles at the upper left area of the screen, click on the *Documents* tile (paperclip icon). Click on *Download All*, the documents will appear in a zip file. Select *Open* and *Extract All* and save in your chosen location.

When all questions on the MDF have been answered the form must be submitted to the default HREC. Once this has happened, the SSA form can be created as a sub-form of the MDF. The SSA form cannot be created before the MDF is submitted to the virtual HREC.

20.2 Types of Research Governance review

Research governance review differs according to the level of risk of the project. Researchers should consult with the RGO within the relevant HHS if they are unsure how to proceed.

The Queensland Health SSA form provides two options for completion – Option 1: the full SSA form, and Option 2: a modified shorter SSA form, which may be used after consultation with the site research governance officer, for single site, low and negligible risk research. Check with the local RGO if uncertain which option to use.

All site-specific documents with updated version details must be uploaded against the form.

Low & Negligible Risk Research – single site

Option 2 of the SSA Form may be completed for Low and Negligible Risk Research – however, if the RGO requests that Option 1 is required, the SSA form must be withdrawn and amended as requested.

Low & Negligible Risk Research, low cost, low resource, multi-site

Queensland Health has introduced a new research governance process for low-risk low resource, low cost (<$10,000.00/site) research projects being undertaken across more than one Queensland Health HHS. Option 2 of the SSA Form may be used if directed by the Research Governance Officer. This is the process to follow:

Researcher contacts RGO at first site to discuss if project is eligible for review under the *Low Cost/Low Resource LNR* model. If the RGO agrees, a full SSA is completed at the first site only.

Alternatively:

If the project is submitted without prior consultation with the RGO, and the RGO considers that project eligible for the Low Coast/Low Resource LNR review, they will notify the researcher.

The RGO at the first site will review the application and if it is still eligible for review under the Low Cost/Low Resource LNR model, the RGO will notify the RGOs at all other participating QH HHSs to alert them to the project.

The researcher must duplicate the original SSA form for each participating Qld Health HHS and upload the relevant Head of Dept. support letter for that HHS along with the Authorisation Letter from the first RGO who undertook the formal review.

Each duplicated SSA is submitted to the relevant RGO where it is progressed for authorisation.

Full SSA (Projects higher than Low & Negligible Risk).

Option 1 of the SSA Form should be selected and all sections completed.

Satellite Site SSA Form for Teletrials projects

Option 1 of the SSA form should be selected and all sections completed, but the RGO should be provided with documents submitted to the Primary Site RGO as well as the site-specific documents for the Satellite Site RGO. See the Teletrials webpage for additional information and Teletrials Toolkit documents or contact the Regional Clinical Trials Coordinating Centre in Queensland for assistance (E: RCCCQLD@health.qld.gov.au)

20.3 Research Contracts

All research projects conducted with collaborators external to Queensland Health require a research contract or agreement. A research agreement may also be required between participating Queensland Health HHSs, particularly where there is transfer of funding for the

research project. Wherever possible, the use of pre-agreed contracts or agreements should be used as these will not require additional legal review if used without amendment.

Appendix 3 contains a list of pre-agreed contacts regularly used by Queensland Health. Appendix 3 also contains a guide to other research contracts which are available on request from the institutional research governance officer.

20.4 Amending or Varying Research Contracts

The terms and content of any pre-agreed contract must not be changed. If changes are made to the body of the contract, the changes will be invalid, and the original wording will prevail.

If a research sponsor wishes to make changes to the Medicines Australia suite of research contracts (MA CTRAs), or the Medical Technology Association of Australia Clinical Investigation Research Agreement (MTAA CIRA), there is guidance on the Medicines Australia website, along with an amendment request template for completion. Please see the list of the list of web links at the beginning of this document and refer to Medicines Australia Clinical Trial Research Agreements (and scroll to Guidance for seeking amendments).

Proposed amendments/variations must be submitted to the SEBS (Southern & Eastern Border States committee) for consideration. Proposed amendments will be given version details and once approved; the agreed variations will be accepted for use within the Australian public health system. There are specific schedules in the various contracts where the agreed amended clauses are to be listed (Schedule 7 or Schedule 4 – depending on the contract).

The costs of legal review of contract amendments/variations are borne by the Sponsor.

For amendments to other contracts, the research team must liaise with the RGO in each institution where the contract will be submitted.

Parties to a Contract

Please contact the Research Governance Officer in the relevant Queensland Health institution if unsure of the correct wording for the parties to the contract.

Who can Sign?

Only persons with delegated authority can sign a research contract on behalf of an institution or Queensland Health; this means the Chief Executive of the Hospital and Health Service, or a delegated officer. Researchers do not have authority to sign the contract unless there is a specific signature block for the Principal Investigator to sign, in addition to the signature block for the Chief Executive or delegate.

Order of Signing

There is no specific order in which contracts/agreements should be signed. However, it is preferred that the Principal Investigator signs the relevant section on the contract or agreement BEFORE it is sent to the research governance office – indicating to the HHS Chief Executive (or delegate) that they have reviewed and agree with the terms and conditions of the agreement or contract.

Electronic Signatures

Queensland Health supports the use of electronic signatures on contracts and research agreements. IT platforms such as *Adobe Sign* or DocuSign *are* compliant with Australian legislative requirements and accepted for use within Queensland Health. Researchers are advised to check with the local research governance office to determine if e-signatures are used within the institution and to confirm the preferred process for contract execution.

> Researcher Tip: Scanned copies of Signatures
>
> Scanned copies of signatures which are cut and pasted into a document are not accepted as e-signatures because they cannot be verified. Acceptable e-signature software requires the signatories to log in and provide a password to the system, or to respond to an invitation to sign. A scanned and pasted copy of a signature does not have this level of security and is not acceptable on legal documents.

20.5 Insurance and Indemnity

Insurance

Where research projects involve collaborators or parties external to Queensland Health, the contract must include reference to insurance and indemnity arrangements.

For commercially sponsored research, the relevant MA CTRAs and MTAA CIRA contain clauses relating to the Insurance to be provided for the project. There are no requirements for specific insurance companies to be used, but the insurance company should have offices or representatives in Australia to facilitate swift processing of any claims that may be made.

Certificates of Currency (insurance certificates) should be submitted with the research governance application, and their expiry dates noted to ensure there is no lapse in cover.

For collaborative or other non-commercial research projects, each institution will generally provide their insurance for the project. The MA CTRA – Collaborative Research Group (CTRA - CRG) contains specific clauses covering this.

Generally speaking, Queensland Health will not provide insurance or indemnity for external parties.

Indemnity

The sponsor of a commercial research project is expected to indemnify Queensland Health against any claims made against Queensland Health because of injuries received from participating in the research, unless the injuries are the result of negligence on behalf of Queensland Health.

Medicines Australia provides two Forms of Indemnity:

Type of Indemnity	When it is used
Standard	For use where the Indemnified Party is providing premises for the conduct of the Study and the HREC Review, **OR** is providing premises only.
HREC Review Only	For use where the Indemnified Party is providing ethics review for a multi-centre clinical Study where the ethics review will be adopted by hospitals, institutions or sites that are independent from the Indemnified Party, **OR** as a Reviewing HREC for a single centre study at a hospital or institution that is independent from the Indemnified Party.

To clarify: the indemnified party is the Queensland Health institution undertaking the study and/or ethics review. A Form of Indemnity is not required for collaborative research projects where the CTRA-CRG is used, because the CTRA-CRG contains indemnity clauses in the terms and conditions.

Generally speaking, Queensland Health will not provide insurance or indemnity for external parties.

21 Project Budgets and Resources

Budgets

Every research project has resource implications, and these must be documented for the research governance review. Individual HHSs set their own requirements regarding business manager review of project budgets. Check with the institutional RGO if uncertain about local tolerance for reporting to the relevant business manager.

For low cost, low resource low risk projects with budgets less than $10,000/site, sign off from the business manager may not be required, but a study budget may still be required as part of the research governance review – check with the RGO if uncertain.

Higher cost projects require a more detailed budget, and local institutional requirements will dictate the process to be followed. However, for all commercially sponsored clinical trials, a copy of Schedule 2 of the contract may be required to accompany the project budget. Sign off from the relevant Business Manager is required.

Resources

Supporting departments must be listed on the SSA form, along with a statement or letter of support from the head of the supporting departments. Quotes for services to be provided may also be requested, as part of the Resource/Budget profile of the project.

22 Study Completion and Archiving

22.1 End of Study Reporting

At the completion of a research project, the researcher must complete a notification to the HREC, providing a summary of the project and including any publications that have been developed. When acknowledgment has been received from the HREC, a similar notification to the research governance office/s should also be provided, unless the HREC and RGO are at the same institution, and the HREC will notify the RGO as per institutional work unit guidelines.

22.2 Storage, Retention and Disposal of Research Data.

Information used in research projects must be stored and retained for specific set periods beyond the completion of the project. Retention times vary according to the type of project.

Depending on the amount of hard copy documentation required to be stored, researchers may need to liaise with the local Health Information Manager with regards to allocation of space for research document retention. It may be advisable to scan hardcopy worksheets and save these on an institutional, protected hard drive, to minimise the volume of hard copy research records to be stored.

The Australian Code for the Responsible Conduct of Research; Management of Data and Information in Research, section 2.3 provides guidance on storage, retention, and disposal of research records. To access this website, please see the list of the list of web links in the beginning of this document and refer to The Australian Code for the Responsible Conduct of Research.

Additionally, the Queensland State Archives also provides guidance for retention and destruction of clinical trials records. To access this website, please see the list of the list of web links in the beginning of this document and refer to Queensland State Archives Health Sector clinical records retention and disposal schedule. Scroll to Downloads, open the .PDF and search on Research.

Where there is different advice about retention periods, always select the longest retention period. Ensure you check the advice before archiving as retention and disposal advice may be amended from time to time.

For commercially sponsored research, the Sponsor should agree to pay for archiving, which may be done off site. However, identifiable information (Consent forms and Patient Identification Log) should be retained within Queensland Health for the duration.

Appendix 1 Research versus Non-Research Activity

Points to consider	Quality Improvement	Research
Definitions	An activity where the primary purpose is to monitor or improve the quality of service delivered by an individual or an organisation is a QA activity. (Ref: NHMRC *Ethical Considerations in Quality Assurance and Evaluation Activities*)	Includes at least, investigation undertaken to gain knowledge and understanding or to train researchers (Ref: NHMRC *The National Statement*)
Purpose	To assess or improve a process, program, or system; OR improve performance as judged by accepted/established standards	To test a hypothesis OR establish clinical practice standards where none are accepted
Starting point	To improve performance	To answer a question or test a hypothesis
Benefits	Designed to benefit a process, program, or system and may or may not benefit patients	Designed to contribute to generalisable knowledge and may or may not benefit subjects
Risks	By design, does not increase patient's risk, with exception of possible privacy/confidentiality concerns	May place subjects at risk and stated as such
Data Collection	Systematic data collection	Systematic data collection
End Point	To improve a program / process / system	Answer a research question
Testing/ Analysis	Compare a program / process / system to an established set of standards.	Statistically prove or disprove a hypothesis (Qualitative research)

Is My Project Research or Quality Improvement?

Will the participants' personal information be used for a purpose other than the purpose for which it was collected?	Yes No
Does the proposed QI activity pose any risks for patients beyond those of their routine care?	Yes No
Does the proposed QI activity impose a burden on patients beyond that experienced in their routine care?	Yes No
Is the proposed QI activity to be conducted by a person who does not normally have access to the patient's records for clinical care or a directly related secondary purpose?	Yes No
Does the proposed QI activity risk breaching the confidentiality of any individual's personal information, beyond that experienced in the provision of routine care?	Yes No
Does the proposed QI activity involve any clinically significant departure from the routine clinical care provided to the patients?	Yes No
Does the proposed QI activity involve randomisation or the use of a control group or a placebo?	Yes No
Does the proposed QI activity seek to gather information about the patient beyond that collected in routine clinical care?	Yes No
Does the proposed QI activity potentially infringe the rights, privacy or professional reputation of carers, health care providers or institutions?	Yes No
Is it intended that the results of the proposed QI activity will be published?	Yes No

If the answer to any of the questions above is *Yes*, the project may not be eligible for consideration as a Quality Improvement project. Researchers are advised to seek advice from the Institutional Quality Assurance officers or local HREC administrator if uncertain.

Useful Clarification tool

Item	Research	Clinical Audit	Service Evaluation / Quality Improvement
Definition	Creates new knowledge; Involves collecting new information; May involve treatments, samples or investigations additional to routine care. Research is only low risk if the only risk is discomfort or inconvenience	Produces information to inform delivery of best care; Measures against a standard; Involves analysis of existing data; May include simple interview or questionnaire.	Defines or judges current care; Measures service without reference to a standard; Involves analysis of existing data; May include simple interview or questionnaire.
Examples	Does a Dengue Fever outbreak impact on Emergency Department presentations {quantitative study}? What are social worker's experiences with patient mortality in Oncology {qualitative study}?	Adherence to a code of clinical practice / procedure / policy How many patients diagnosed with [insert health condition] re-present to hospital within 60 days after discharge? Does the antibiotic usage for (insert health condition) comply with the antimicrobial guidelines?	Are the Diabetes Clinic outpatients satisfied with home-visits from a dietician? Evaluation of a new technique, tool or model of care

Case Report versus Case Series	
Case Report A case report involves the write up and publication of an interesting case. It is not research. In some situations, a second case may also be discussed and treated as a case report. Ethics approval is not required unless it is a condition for publication. Consent should be obtained from every person or their legally authorised representative. However, if it is not practicable to obtain consent, a PHA grant may be required if potentially re-identifiable information will be disclosed outside Queensland Health. HREC Approval is a requirement for the PHA application.	**Case Series** Generally, involves three or more cases and is deemed to be research. Ethics approval is required. Consent should be obtained from every person or their legally authorised representative. However, if it is not practicable to obtain consent, a PHA grant may be required if potentially re-identifiable information will be disclosed outside Queensland Health. HREC Approval is a requirement for the PHA application.

Appendix 2 Clinical Trial Phases and Stages

(Ref: Therapeutics Goods Administration: *Australian Clinical Trial Handbook*, ver 2.3 Nov 2020)

Clinical Trial Phases for Medicines & Biologicals		
Phase	**Description**	**Objectives**
Phase 0	Human pharmacology: Micro-dosing, involving 10-15 participants. Involves dosing a limited number of humans with a limited range of doses for a limited period of time	Assess pharmacokinetics: Gather preliminary data on pharmacokinetics and bioavailability to determine if the drug behaves as expected from preclinical studies
Phase I	Human pharmacology: 10-100 participants: May involve the first administration to humans, usually to small numbers of healthy volunteers or to patients	Safety and tolerance: Define or describe pharmacokinetics and pharmacodynamics Determine dosing Explore drug metabolism and drug interactions Identify preferred routes of administration Phase Ia: Single ascending dose Phase Ib: Multiple ascending dose
Early phase trials	Early phase trials are no longer defined as traditional Phase I trials. Early phase trials can be broadly defined as non-therapeutic, exploratory trials in human participants who may be healthy volunteers or have a specific disease. Increasingly, trial sponsors are submitting early phase trials to HRECs that combine a number of different study parts within an integrated trial protocol.	
Phase II	Therapeutic exploratory: 100-300 participants. May be undertaken in a larger group of	Efficacy and safety: Phase IIa:

	human patients (several hundred)	Demonstrate clinical efficacy or biological activity through pilot studies Explore therapeutic dose range Phase IIb: Determine optimum therapeutic dose and regimen (with efficacy as primary endpoint) Resolve uncertainties regarding the design and conduct of subsequent trials
Phase III	Therapeutic confirmatory: 300-3000 participants.	Safety, efficacy or effectiveness Phase IIIa: Determine the therapeutic effect in patient populations for which the drug is eventually intended Provide a definitive assessment of risk-benefit balance (to support drug registration or change in clinical practice) Phase IIIb: Increase patient exposure and support marketing claims or publication
Phase IV	Therapeutic use: Involves thousands of participants	Post marketing surveillance or resolution of treatment uncertainties Monitor safety in real world populations To refine knowledge of the risk-benefit balance, detect rare or long-term adverse effects, drug interactions Pharmacoeconomics to gather data in support of the use Comparative effectiveness and community based research (sometimes described as Phase V trials) Trial combinations with existing products
Clinical Trial Stages for Medical Devices		
Phase	**Description**	**Objectives**
Pre-market pilot	Usually involves a small group of human patients (10-30 participants)	Exploratory investigations to determine preliminary safety and performance information to plan design modifications or provide support for a future pivotal study.

		Includes first in human and feasibility studies or proof of concept.
Pre-market pivotal	Involves hundreds of participants	Confirmatory investigations to evaluate performance and safety for a specified intended use to satisfy pre-market regulatory requirements
Post-market	Involves thousands of participants	Confirmatory investigations to establish performance and safety, for example, in broader populations. OR Observational investigations or surveillance to gain better understanding of device safety, long-term outcomes, health economics

Appendix 3 Pre-Agreed Research Contracts

The websites where these contracts are found are listed in *Websites Table* on pages 4 and 5.

Name of Agreement	Used for
Medicines Australia Clinical Trial Research Agreements (MA CTRAs)	Clinical Drug Trials, as follows:
Standard Contract: (MA CTRA Standard)	Sponsor is engaging directly with participant sites (Phase 0-III)
Contract Research Organisation (MA CTRA-CRO)	Sponsor has engaged a contract research organisation to conduct the project on its behalf (Phase 0-III)
Collaborative or Cooperative Research Group studies (MA CTRA-CRG).	Used for collaborative group clinical trials.
Phase 4 Clinical Trial (Medicines)	Used for post marketing registry / Phase IV studies
Medical Technology Association of Australia Standard Clinical Investigation Research Agreement (MTAA CIRA)	Device trials (all stages)
Multi-Jurisdictional Multi-Party non Clinical Trial Collaborative Research Agreement	The Multi-Jurisdictional Multi-Party non-Clinical Trial Collaborative Research Agreement was endorsed by all jurisdictions at the Clinical Trials Project reference Group meeting held on the 13th April 2022. This follows extensive consultation across the research sector. This template agreement is non mandatory and follows the model of the Medicines Australia and Medical Technology Association of Australia suite of clinical trial research agreements. Please note than any change to any of the clauses shall be made between the contracting parties and their respective legal counsel in Schedule 1. Changes to clauses in this agreement will not be reviewed by the Southern Eastern Border States (SEBS) panel.

	Multi-Jurisdictional Multi-Party non-Clinical Trial Collaborative Research Agreement – Final template (July 2022)
Queensland Public Sector Health System Multi-site Research Collaboration Agreement Standard terms Project Schedule template	Collaborative research agreement for use between Queensland Health sites only.
Teletrials Subcontract	Used in clinical trials conducted under the Teletrials model. The subcontract is used between a Primary Site and its Satellite Site/s
Brisbane Diamantina Health Partners Research Passport Agreement	Used for low-risk research projects conducted between two or more collaborating BDHP partners. **Not to be used for clinical trials** or research where the level of risk is higher than low risk.
The following contracts and agreements are obtained through the Research Governance Office in Queensland Health Hospital and Health Services. Please contact the local RGO to obtain the preferred site version.	
Data Transfer Agreement	Used where information only is being provided from an institution to a researcher or research database. The institution providing the information has no other real involvement in the project.