Standard Operating Procedures

Queensland Health Research Governance Officers

Queensland Government

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Amendment history

Version	Date	Author/s	Amendment details
1.0	2008	OHMR	New
2.0	2009	OHMR	Annual review
3.0	Feb 2010	OHMR	Mutual Acceptance update
4.0	June 2010	OHMR	Mutual Acceptance update
5.0	Nov 2013	HMR	National Mutual Acceptance update
6.0	April 2022	OPMR	Reflect current REG HSD and National Mutual Acceptance update

Standard Operating Procedures for Queensland Health Research Governance Officers.

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Acknowledgements

These Standard Operating Procedures (SOPs) have been developed by the Office of Precision Medicine (OPMR), Prevention Division, Department of Health (the department) with input and contributions from Queensland Hospital and Health Service Research Governance Officers (RGOs), Human Research Ethics Committee (HREC) Administrators, HREC Chairs, HREC members, the Aboriginal and Torres Strait Islander Health Division and research staff.

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Introduction

Purpose

Queensland Health (comprising the Department of Health (the department) and 16 independent Hospital and Health Services (HHSs) must apply an appropriate research governance framework. Research governance can be defined as the framework by which institutions, investigators and their managers share responsibility and accountability for research conducted according to ethical principles, scientific, regulatory and professional standards and the principles of risk management. Research governance is a local institutional due-diligence assessment. It encompasses the assessment of legal, financial, regulatory and contractual issues. This standard operating procedure (SOP) outlines how a Research Governance Officer (RGO) assesses this in practice.

Effective research governance ultimately depends on the commitment of all parties to understand and administer their roles and responsibilities. Ethical and scientific review by an appropriately constituted Human Research Ethics Committee (HREC) is just one aspect of a broad system of oversight and management of the conduct of research.

Systems and processes to ensure good research governance must facilitate, not hinder, quality research. This requires an exercise of judgement based on an understanding of the context, research methods and risks involved by all parties involved in the governance of research.

The SOP outlines Queensland Health's responsibilities which are consistent with the following regulatory and guidance documents listed below, as updated from time to time.

Reference documents:

• NHMRC National Statement on Ethical Conduct in Human Research (Updated 2018)	Link	(National Statement)
• NHMRC Australian Code for the Responsible Conduct of Research (2018)	Link	(the 2018 Code)
• Integrated Addendum to ICH E6(R1): Guidelines for Good Practice ICH E6(R2) (2016)	Link	(ICH-GCP)
• *Therapeutic Goods Act 1989* (Cth) and *Regulations 1990* (Cth)	Link	(TG Act and TG Regs)
• NHMRC Guidelines approved under Section 95A of the *Privacy Act 1988* (Cth)	Link	
• *Hospital and Health Boards Act 2011* (Qld)	Link	(HHB Act)
• *Transplantation and Anatomy Act 1979* (Qld)	Link	(TA Act)
• *Public Health Act 2005 (Qld)* Ch 6 Part 4	Link	(PH Act)

• National Mutual Acceptance, Single Ethical Review of Multicentre Human Research Projects (NMA SERP), 'Standard Principles for Operation' (November 2021)	Link
• NHMRC Guide to managing and investigating potential breaches of the Australian Code for the Responsible Conduct of Research (2018)	Link
• NHMRC Framework for Monitoring: Guidance for the national approach to single ethical review of multi-centred research (January 2012)	Link
• NHMRC Research Governance Handbook: Guidance for the national approach to single ethical review (2011)	Link
• Queensland Health Research Management Policy QH-POL-013:2015 (2015 – Version 2)	Link
• NHMRC Ethical conduct in research with Aboriginal and Torres Strait Islander Peoples and communities	Link
• Genomic Partnerships: guidelines for genomic research with Aboriginal and Torres Strait Islander peoples of Queensland (2019)	Link
• Australian Commission on Safety and Quality in Health Care (ACSQHC) National Clinical Trials Governance Framework and User Guide	Link
• Guideline for researchers – disclosure of confidential information	(Link TBA)
• Queensland Health Research Ethics and Governance Health Service Directive QH-HSD-035	(Link TBA)

Scope

These SOPs apply to all research that takes place in Queensland Health. This means research -

(i) conducted at sites under the control of the department and/or an HHS
(ii) involving participants, their tissue or data accessed through the department and/or an HHS.

It applies to the full spectrum of research: biomedical, clinical, public health and health services research.

For this document, the meaning of research is that used in the 2018 Code namely:

'The concept of research is broad and includes the creation of new knowledge and/or the use of existing knowledge in a new and creative way so as to generate new concepts, methodologies, inventions and understandings. This could include synthesis and analysis of previous research to the extent that it is new and creative.'

Activities other than research are considered outside the scope of this document. These may include quality assurance or improvement activities, clinical audit, management of health services activities and teaching.

Implementation

This SOP promotes a consistent approach for Queensland Health RGOs when reviewing Site Specific Assessment (SSA) applications. The document outlines a minimum standard for applications and implementation where ethics approval of a research project has been granted by a Human Research Ethics Committee (HREC).

Institutions may develop their own SOPs (consistent with these Queensland Health RGO SOPs) and additional work instructions to manage local review processes. Local RGO requirements should be made publicly available on the relevant Queensland Health institution's website.

Queensland Health RGOs will direct researchers to submit SSA applications and post authorisation forms along with all required documentation using Ethics Review Manager (ERM) or its replacement.

Definitions and abbreviations

Adverse event (AE)	**Investigational Medicinal Product (IMP) Trials** 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. For more information: NHMRC Safety monitoring and reporting in clinical trials involving therapeutic goods.
Adverse event (AE)	**Investigational Medical Devices (IMD) Trials** Any untoward medical occurrence, unintended disease or injury, or untoward clinical signs (including abnormal laboratory findings) in participants, users or other persons, whether or not related to the investigational medical device.

	Note: This definition includes events related to the investigational medical device or the comparator. This definition includes events related to the procedures involved. For users or other persons, this definition is restricted to events related to investigational medical devices. For more information: NHMRC Safety monitoring and reporting in clinical trials involving therapeutic goods.
Adverse event (AE)	An incident in which unintended harm resulted to a person involved health care research. (Modified from the definition of adverse events in the Open Disclosure Standard published by the Australian Commission on Safety and Quality in Health Care).
Applicant	The Principal Investigator (PI) for single site studies and Coordinating Principal Investigator (CPI) for multi-site studies who are responsible for and sign off all ethics applications.
Associate Investigator (AI)	An investigator who assists with the conduct of a study under the direction of the PI. Synonymous with Sub-Investigator.
Australian Code for the Responsible Conduct of Research (the 2018 Code)	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 more information: Australian Code for the Responsible Conduct of Research (the 2018 Code).
Calendar Days	Calendar days means every day on the calendar, including weekends and public holidays.
Certified HREC	Means a HREC which has had its processes assessed and certified under the NHMRC National Certification Scheme. For more information: National Certification Scheme for the ethics review of multi-centre research.
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 Principal Investigator (PI) to be responsible for coordinating the conduct of a research study, under the direction and supervision of the PI. Synonymous with Site Coordinator, Clinical Study Coordinator, Clinical Trial Coordinator, Research Nurse.
Clock day	Means each calendar day after a valid application has been received and is being processed excluding time taken for the applicant to respond to queries with further information that enables processing to recommence. That is, clock days are not a measure of total time elapsed since a valid application is received but, instead, are a measure of processing time. See Stop Clock facility definition.
Confidential information	Means information designated as 'confidential information' under health portfolio legislation'. For example, as defined in section 139, Part 7 (Confidentiality) of the HHB Act or section 76, Division 3, Part 2, Chapter 3 (Notifiable Conditions) of the PH Act.
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 corresponding with the Reviewing HREC throughout a multi-centre study and passing on information from the Reviewing HREC to the Sponsor and the PI at each site conducting the research. For single site studies, the terms CPI, Coordinating Principal Researcher, Site PI and PI are all synonymous.
Department of Health (the department)	Means the department of the Queensland Government named 'Queensland Health' or its successor.
DoRA2.0	Database of Research Activity 2.0 (DoRA) is a publicly accessible, searchable database which holds research data from ERM and presents it in a format to allow researchers and other interested public stakeholders to search for and view summary level information about research being conducted in Queensland Health.

Ethics Review Manager (ERM)	Ethics Review Manager (ERM) is a secure web-based research application system used 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. Note: ERM has replaced Online Forms/AU RED in Queensland Health.
ERM Project ID	The ERM Project ID is a unique number automatically assigned to projects and is generated when an applicant creates an application. It remains constant for the life of the submission.
Forensic and Scientific Services (FSS)	Conducts forensic, public health and environmental testing and research. FSS is part of the department. For more information: Forensic and Scientific Services (FSS).
Good Clinical Practice (GCP)	The International Council on Harmonisation (ICH) Guideline for Good Clinical Practice as adopted by the Therapeutic Goods Administration in Australia. The ICH Guideline is an international ethical and scientific quality standard for designing, conducting, recording and reporting trials that involve the participation of human subjects. For more information: https://www.tga.gov.au/publication/note-guidance-good-clinical-practice.
Office of Precision Medicine and Research (OPMR)	The Office of Precision Medicine and Research (OPMR) is responsible for consultation, development and review of State-wide research ethics and research governance policies. OPMR provides a central point of contact for researchers, Queensland Health HREC Chairs and members, Site Coordinators, RGOs and study Sponsors seeking advice and direction on ethical and governance issues associated with the conduct of research in Queensland Health. OPMR was formally known as Health Innovation, Investment and Research Office (HIIRO).
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 HHB Act.
Human Research Ethics Application (HREA)	The Human Research Ethics Application (HREA) is a streamlined and contemporary ethics application that uses dynamic content and guidance to assist researchers consider and address the principles of the National Statement.
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 human research projects. 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 might include Aboriginal and Torres Strait Islander peoples' participation.
HREC Administrator	An employee of an institution where a study will be conducted or overseen, 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.
HREC Chair	The chairperson of a HREC.
Identifier	Details attached to data such as name, image, date of birth or address, attribute or group affiliation, from which an individual is reasonably identifiable.
Low Risk 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.
Multi-Centre Research (MCR)	Includes research conducted through the collaboration of at least two unique institutions that may be situated in more than one State or

	Territory or within a single jurisdiction. It does not refer to research being conducted at several sites or locations of a single institution.
National Mutual Acceptance (NMA)	Means the national approach to single ethical review of multi-centre research in which participating States and Territories of Australia have agreed to accept the scientific and ethical review of an HREC from a public health facility located outside of the institution's State/Territory. For more information: National Mutual Acceptance (noting that all states have agreed that Victoria is the web site host for all NMA documentation).
National Statement on Ethical Conduct in Human Research (2007) (Updated 2018) (the National Statement)	A guidance document developed by the National Health and Medical Research council (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. For more information: National Statement on Ethical Conduct in Human Research (2007) (Updated 2018).
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: National Statement on Ethical Conduct in Human Research (2007) (Updated 2018)
Opt-Out consent 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. For more information: National Statement on Ethical Conduct in Human Research (2007) (Updated 2018)
Personal Information	In accordance with the *Information Privacy Act 2009* (Qld): 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* (PH Act)**	The *Public Health Act 2005* (Qld) provides the basic safeguards necessary to protect public health through cooperation between the state government, local governments, health care providers and the community. Applications for the release of confidential information for the purposes of research are administered under Section 280 of the PHA.
Principal Investigator (PI)	The Investigator responsible for the overall conduct, management, monitoring and reporting of the research study at an individual site. For multi-centre studies, a PI does not have CPI responsibilities. The PI is responsible for submitting the Site Specific Assessment (SSA) for site authorisation and liaises with the site RGO throughout the life of the research project. The PI is responsible for relevant communication with and reporting to the CPI with respect to all information related to the research that requires submission to the Reviewing HREC. For multi-centre studies, a PI does not have CPI responsibilities. For single site studies, the terms CPI, Coordinating Principal Researcher, Site PI and PI are all synonymous.
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. For more information: www.safetyandquality.gov.au May include patient satisfaction surveys, surveillance and monitoring and clinical audits. Noting, there is no RGO involvement if a HREC has granted an exemption from HREC review.
Quality Improvement Activity (QIA)	Quality improvement is the combined efforts of the workforce and others – including consumers, patients and their families, researchers, planners and educators –to make changes that will lead to better patient outcomes (health), better system performance (care) and better professional development. Quality improvement activities may be undertaken in sequence, intermittently or on a continual basis. QIAs can be described as the assessment of current practices to see whether or not they are working or assessing current practice against a procedure, standard or guideline. These projects are usually classed as non-research and are assessed by the HREC Chair or delegate (according to processes set out in the HREC Terms of Reference) when the applicant wishes to publish the results of the project external to Queensland Health. Noting, there is no RGO involvement if a HREC has granted an exemption from HREC review.
Queensland Clinical Trials Coordination Unit (QCTCU)	The Queensland Clinical Trials Coordination Unit (QCTCU) is a unit of OPMR.

Queensland Health	Means the public sector health system which is comprised of the HHSs and the department pursuant to section 8 of the HHB Act.
Registered HREC	Means a committee registered by the NHMRC and constituted under the guidance of the National Statement to conduct the ethical and scientific review of a human research project.
Research Authorisation	Authorisation is issued by the department/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 department/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 target time given for a research governance decision (that is authorisation or not) is 25 clock days from receipt of a valid research governance application.
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 department/HHS CE or delegate as to whether a research study should be granted authorisation at that site and • monitoring authorised research at the site to ensure it meets appropriate standards (Research Governance).
Research Governance process	The Research Governance process is a due diligence assessment separate to ethical review of a proposed research project based on information provided in the governance application. The RGO assesses the appropriateness of site involvement in a study including by having regard to resource implications, 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. The research governance process is completed when the RGO makes a recommendation to the department/HHS CE or delegate. If it is authorised by the department/HHS CE (or their delegate), and subject to HREC approval, the study may commence at that institution/HHS.
Reviewing HREC	A HREC that has been allocated to review a human research study.
Satellite Site	Means a satellite site that is located in a geographically separate health facility from the primary site and responsibility is delegated by the primary site (clinical trial site) to perform activities associated with the conduct of a clinical trial and to support trial accessibility of remote participants to a clinical trial.

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: NHMRC Safety monitoring and reporting in clinical trials involving therapeutic goods
Significant Safety Issue (SSI)	A safety issue that could adversely affect the safety of participants or materially impact on the continued ethical acceptability or conduct of the trial.
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 Site Coordinator, Clinical Study Coordinator, Clinical Trial Coordinator, Research Nurse.
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 that 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).
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.
Sponsor	An individual, company, institution or organisation which takes responsibility for the initiation, management, and/or financing of research. For more information: www.tga.gov.au
State Specific Modules	Victoria, Western Australia and Norther Territory have developed additional forms and 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: www.clinicaltrialsandresearch.vic.gov.au.
Stop Clock facility	'With Clock' is a measure of the time taken for processing of the application by the administering body only. The clock stops when the application leaves the administrator and is the responsibility of the

	investigator, trial coordinator, sponsor or CRO to provide further information about the application. The clock re-starts when a response is received from the investigator/trial coordinator/sponsor/CRO. 'Without Clock' is a measure of the total timeline –including both the time taken to process the application by the administering body, and the time to respond to queries by the investigator/trial coordinator/sponsor/CRO. For HREC applications: the time when the 60-day clock is stopped while awaiting a satisfactory response from the applicant to a written request from the HREC for further information or clarification. The clock will re-start automatically when a response from the applicant is logged in to ERM. For SSA applications, the time when the 25-day clock is stopped while awaiting a satisfactory response from the applicant to a written request from the RGO for further information or clarification.
Study Site	Means the location(s) under the control of the institution where the study is conducted.
Suspected Unexpected Serious Adverse Reaction (SUSAR)	A SUSAR is defined as an adverse reaction that is both serious and unexpected. A serious adverse reaction is 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. For more information: NHMRC Safety monitoring and reporting in clinical trials involving therapeutic goods
Therapeutic Goods Administration (TGA)	The Therapeutic Goods Administration (TGA) is the agency responsible for regulating therapeutic goods in Australia. For more information: https://www.tga.gov.au.
Transplantation and Anatomy Act 1979 (Qld) TA Act	The *Transplantation and Anatomy Act 1979* (Qld)is an Act to make provision for and in relation to the removal of human tissues for transplantation and other medical and scientific purposes, for post-mortem examinations, for the definition of death, for the regulation of schools of anatomy, and for related purposes.

Twenty-five (25)-day clock	The period of 25 clock days allowed for the SSA review by the department/HHS CE or delegate of a research application. The clock starts on receipt of a valid SSA.
Unanticipated Serious Adverse Device Effect (USADE)	Serious adverse device effect which by its nature, incidence, severity or outcome has not been identified in the current version of the risk analysis report
Urgent Safety Measure (USM)	A measure required to be taken in order to eliminate an immediate hazard to a participant's health or safety.
Validation	A preliminary administrative review carried out by an RGO to verify that all applicable documentations are submitted prior to review.

1. RGO SOP 01: Research governance review – standard workflow

General guidance

1.1. The research governance process is a mandatory site specific review which is required to be undertaken prior to the commencement of a research study at a site. It is separate from the ethics review undertaken by the Reviewing HREC and/or the risk reviews undertaken by a Low and Negligible Risk (LNR) review panel (as applicable).

All governance applications are to be submitted using ERM (or its replacement).

1.2. The RGO must undertake an assessment of the research project based on the information provided in the SSA Form. This assessment must consider the following matters:

a) Head of Department (HoD) / Executive Director approval. Evidence in the form of endorsement, which indicates appropriateness of the research project in terms of the research goals of the department/HHS and whether the institution wishes the research to be conducted at its site, i.e., does this research fit within the department/HHS research strategy.
b) Sign off by relevant Business/Finance manager to indicate the resource (financial, human, equipment, infrastructure) implications of the research project for the department/HHS are appropriate, accountable and available.
c) The expertise and experience of researchers (noting the HoD support for the researcher(s) and project), ensuring that relevant training for researchers has been, or will be, conducted before the research commences at the site.
d) That due consideration be given to the relevant laws, policies and codes of conduct relating to matters such as privacy, confidentiality, consent, bio-safety, professional standards, contracts, intellectual property and radiation safety.
The legal requirements of the research project
e) An appropriate on-site monitoring is enabled for research projects (related to research conduct, risk levels of research and Serious Adverse Events (SAEs) at the recommendation of the Reviewing HREC or in response to local events.

1.3. In conducting the assessment, the RGO may seek advice/endorsement from other relevant personnel as is considered necessary. This may include communicating with the reviewing HREC/other RGOs and third-party representatives as required, for further clarification and approval. However, the RGO's role is not to duplicate the ethics review. Collaborative communication is encouraged to streamline processes and to reduce duplication.

1.4. Parallel governance and ethics review are recommended for all research. When requested, Research Governance Officers (RGOs) will accept research governance applications in parallel with HREC applications. Note, Governance authorisation to commence a project cannot be issued until the ethics approval has been granted. Care should be taken with

parallel review processes as a HREC can request major changes to a research protocol that has been sent out to delegates for signatures prior to the HREC review being completed.

1.5. The Principal Investigator (PI) at each site should consult participating and/or supporting departments for their acceptance of the project prior and/or during the governance application process.

1.6. The RGO ensures that the designated personnel have assessed the nature of the research project and its implications for the department/HHS. The RGO should not reassess or override the opinion of the designated personnel without consultation. The minimum assessment that should take place is as follows:

a) HoDs/Executive Director/General Manager or delegate approval of:
   I. the recruitment process at the site
   II. the human resource impact to the department/s involved i.e., what is the time commitment of staff and the total number of staff involved
   III. the material resource impact i.e., will the project require the use of equipment, interview/treatment rooms and how will the resources be provided/paid
   IV. consideration of risk and patient safety (particularly for clinical studies/clinical trials).

b) Business Manager or delegate approval of the financial resource impact is required. This requirement is waived for research studies costing under $10,000 at a site. Financial delegation will be exercised by the HoDs in this case.

   I. a budget must be uploaded for funded and/or in-kind contribution (no funding). This research budget must be adequate to undertake the study. Please note that if research is considered a part of a researcher's normal duties, their salary is NOT to be included in in-kind cost calculations for non-commercially sponsored research.
   I.I submission of the Research Cost Centre/Internal Order Number (ION) as applicable.

c) Legal review of the contract:

   I. For each research arrangement for which HHSs and, where relevant, the department collaborate, the collaborating parties must ensure that an appropriate contractual arrangement is in place between them to mitigate risks to the Queensland public sector health system and clarify the roles and responsibilities of, and allocate risks between, the parties. While there is no mandatory form of contractual arrangement, standard terms and conditions developed through consultation between the department and the HHSs that the collaborating parties may consider for use are available on request to OPMR.
   II. The legal review of the relevant contract(s) should consider:

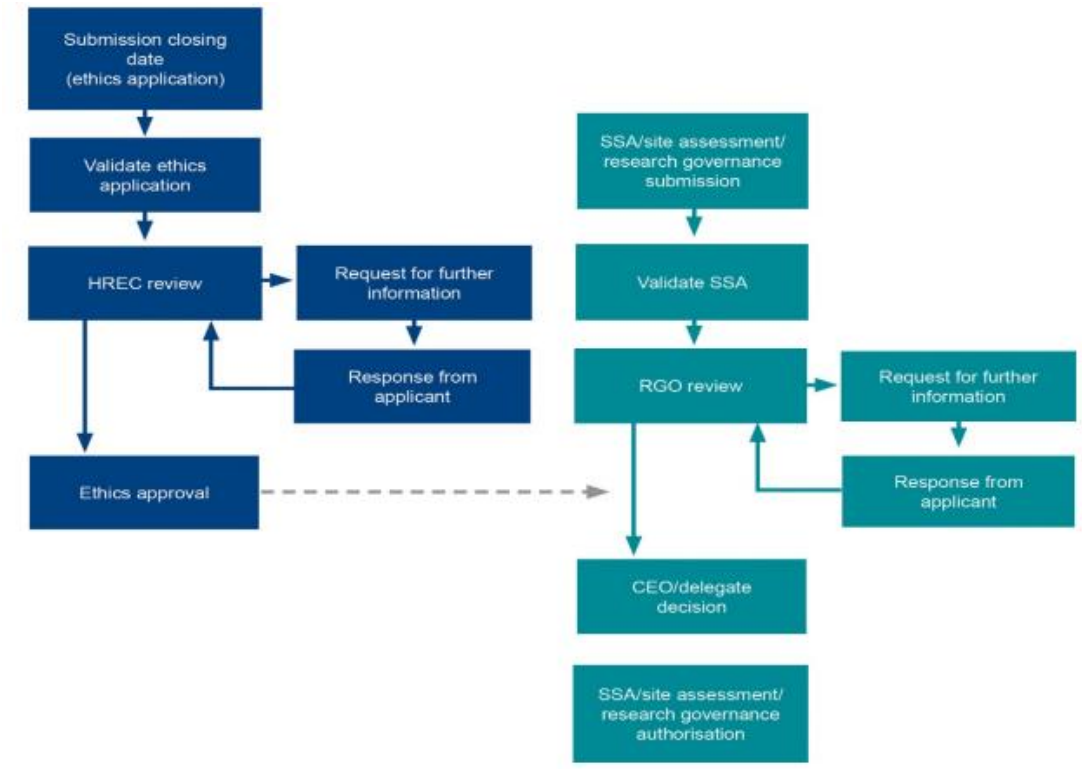
- Is a legally binding contract in place that sets out the responsibilities and obligations of each party involved in the research project?
- Has the contract undergone previous legal review by the relevant Queensland Health / HHS legal team or is it a pre-approved standard agreement template?
- Has intellectual property impact been considered i.e., who owns the intellectual property generated through the course of the project and how is this to be distributed in the future?

d) Insurance and indemnity (only as applicable):
   I. What are the insurance and indemnity provisions for the project? What level of insurance cover is being proposed and is it appropriate for the type of study being undertaken?
   II. Check for conflict of interest and how this has been mitigated.

e) Ensuring the relevant authorisations are in place (if applicable):
   I. PHA grant (approval) letter
   II. Queensland Civil and Administrative Tribunal (QCAT) approval
   III. Institutional Biosafety Committee (IBC) approval
   IV. NHMRC Gene and Related Therapies Research Advisory Panel (GTRAP) or Cellular Therapies Advisory Committee (CTAC) approval
   V. NHMRC Licensing Committee approval
   VI. Australian Radiation Protection and Nuclear Safety Agency (ARPANSA) code compliance
   VII. Evidence of GCP compliance (refer to National Clinical Trials Governance Framework)
   VIII. HREC Ethics Approval
   IX. LNR Risk Approval
   X. Forensic Scientific Services Human Ethics Committee (FSS-HEC) approval where research involves access to coronial material
   XI. Data Custodian approval.

1.7. The RGO reviews all research governance applications and provides an outcome recommendation to the department/HHS CE or delegate who retains the authority for authorising the conduct of research at the site.

Standardised Research Ethics and Governance Workflow



Electronic signatures

1.8. The SSA Form can be signed electronically, by a wet ink signature or by uploading of other evidence by the PI and HoD (if applicable). It is the responsibility of the PI / CPI (as applicable) to ascertain which method is accepted by each HHS and the department.

As per the Queensland Health Financial Management Practice Manual and Use of electronic approval-COVID-19 FMPM Standard 7.3.2, noting that access to this document is only available to QH employees through the QH Intranet .

2. RGO SOP 02: Site Specific Assessment (SSA) Form- Overview

Purpose of this form

2.1. Applications for SSA are to be prepared and submitted by the PI / CPI (as applicable).

2.2. The PI / CPI (as applicable) may select one of the options below to create an SSA Form to make an SSA application in ERM:

Option 1. To submit a NEW SSA Form.

Option 2. As directed by the RGO. For example, to create a non-lead SSA Form for a low risk/low cost multi-centre research process or otherwise when a full SSA completion is not required.

FORM CONTENTS

Intellectual Property, Outcomes and Translation	Intellectual Property	Outcomes and Translation
Other Project Documents	Other documents	
Declarations and Signatures	Head of Department Signature Page	PI Signature Page

Project details

2.3. The 'Project Details' section enables the RGO to liaise with the ethics review body if required and ensures that the applications flow to the correct RGOs in ERM. It is the responsibility of the PI / CPI (as applicable) to insert the correct HREC review reference number and to check the relevant local site location/s.

2.4. Anticipated start and finish dates

The provision of anticipated start and finish dates (expected duration of a project) enables the site to consider whether the requested use of facilities, staff and resources will be available and whether it is appropriate to allow the research project to commence at the site. It also enables the site to consider whether there are other competing studies being undertaken concurrently at the site. There is a difference between anticipated start and finish dates and HREC approval/RGO authorisation date.

Research personnel

2.5. The 'Research Personnel Information' section relates to the PI / CPI (as applicable) organisation / employer and qualifications such as Good Clinical Practice (GCP) for clinical trials.

Training

2.6. The 'Training Information' section is a declaration that the PI / CPI (as applicable) and/or research team has had training or experience in research methods (including informed consent), GCP and procedures specific to the research being undertaken at the site. All other researchers who will assist in the conduct of the research, under the direction of the PI / CPI (as applicable) (e.g., 'associate investigators' or 'sub-investigators') should be included in this section. In addition, all medical staff involved in the research must make a declaration about their current credentials. GCP training must be kept current i.e., if revisions are made to ICH-GCP then evidence of training including that revision must be available. If there is a knowledge deficit, the PI should outline how this will be rectified, i.e., who is providing the training and when this is going to occur.

2.7. A local SOP that guides the process for checking researchers and their qualifications and a process for recording researcher GCP training is recommended.

Participants and Recruitment

2.8. Recruitment methods should be compliant with all relevant privacy policies and legislation at both Federal and State levels and it should be established whether the identified participant group is appropriate and available at the study site.

Research involving access to coronial material

2.9. Research involving access to coronial material must be referred to the Queensland Forensic and Scientific Services Human Ethics Committee (FSS-HEC) for ethics and legal approvals prior to authorisation. Email enquiries should be directed to FSS_HEC@health.qld.gov.au

Impaired capacity of adult to consent to clinical research participation

2.10. Where a Research Application is for clinical research and proposes to include in its cohort persons who are over the legal age of consent but lack capacity to give informed consent the PI / CPI (as applicable) must also obtain approval (or consent in the case of special medical research or experimental health care) from Queensland Civil and Administrative Appeals Tribunal (QCAT) for the proposed clinical research project. The matters that QCAT will need to be satisfied of are set out in section 72 and 74C of the *Guardianship and Administration Act 2000* (Qld) and includes that the study has HREC approval.

2.11. After a 'clinical research' (defined in section 74A of the *Guardianship and Administration Act 2000* (Qld) and does not include 'special medical research or experimental health care') project has been approved by QCAT, the *Guardianship and Administration Act 2000* (Qld) sets out who may consent to the adult participating in the approved research. The PI / CPI (as applicable) is responsible for ensuring that consent is obtained from the correct substitute decision-maker.

2.12. More information has been published here: https://www.qcat.qld.gov.au/matter-types/clinical-research

Research involving biospecimens (adults and children)

2.13. 'Human biospecimens' is a broad term that refers to any biological material obtained from a person including tissue, blood, urine, sputum and derivate of the same, such as cell lines. Section 3.2.10 of the National Statement states where biospecimens were obtained domestically or via importation prior to December 2013, the biospecimens may continue to be used in Australia for approved research provided that the researcher's institution ensures that:

(a) there is sufficient evidence that the samples were obtained in a manner consistent with any prior guidelines and/or the accepted ethical practice at the time of collection, and
(b) the proposed research for which the biospecimens will be used is within the scope of the consent provided by the donor(s).

2.14. Please refer to Chapter 3.2 of the National Statement for further information.

2.15. Please refer to the Queensland Transplantation and Anatomy Act 1979 (TA Act) sections 21B (for adults) and 21C (for children). The TA Act amongst other things, regulates the removal of tissue by living persons, including blood, for approved research. Section 21B of the TA Act provides that the removal of tissue (including blood) from an adult's body is authorised if done for the purpose of approved research and consent is given as required under the National Statement.

2.16. For noting, applications to create a biobank must only be considered by the full HREC.

2.17. If the research requires access to tissue samples or other data sources held by Clinical and State wide Services (CaSS) (including data in AusLab and AusCare), researchers may require approval from CaSS. More information on accessing tissue samples or data is available here: https://www.health.qld.gov.au/public-health/pathology-queensland

Research involving genetic technologies

2.18. A licence may be required from the Office of the Gene Technology Regulator for certain research involving live and viable organisms that have been modified by gene technology. More information is available here: https://www.ogtr.gov.au/apply-gmo-approval.

Research involving children

2.19. Eligible paediatric multi-centre research should only be reviewed once only by a NHMRC certified paediatric HREC under the following:

(a) National Mutual Acceptance Scheme
(b) the Memoranda of Understanding between the Department of Health and institutions external to those within Queensland Health regarding mutual acceptance/recognition of ethical and scientific review of multi-centre research studies.

Research involving Aboriginal and Torres Strait Islander Peoples including coincidental recruitment

2.20. It is the role of the Reviewing HREC to assess the appropriate consultation with impacted communities.

For noting - research that specifically involves Aboriginal and/or Torres Strait Islander people, researchers should ensure appropriate community input, for example through the Queensland Aboriginal and Islander Health Council (QAIHC).

RGOs should ensure all researchers who propose to conduct research projects which involve Aboriginal and/or Torres Strait Islander people have considered and complied with (as applicable):

- NHMRC Ethical conduct in research with Aboriginal and Torres Strait Islander Peoples and communities — Link
- NHMRC Keeping research on track II — Link

- AIATSIS Code of Ethics for Aboriginal and Torres Strait Islander Research — Link
- Guide to applying the AIATSIS Code of Ethics — Link

- Genomic Partnerships: Guidelines for genomic research with Aboriginal and Torres Strait Islander peoples of Queensland — Link

Confidentiality and Data Protection Access to data

Lawful authority to disclose/access public patient information

2.21. In addition to ethics approval, where the research requires a designated person to disclose confidential information about a patient to a researcher, the researcher must identify a lawful authority for the use or disclosure of that information. Lawful authority may include:

a) disclosure with patient consent (adult with capacity; or a child with sufficient age and mental and emotional maturity to understand the nature of consenting to the disclosure) or, where applicable, patient's guardian consent (section 144 of the HHB Act)
b) a decision to give information in accordance with Chapter 6, Part 4 of the PH Act
c) disclosure under section 150A of the HHB Act from a designated person to a researcher for the purposes of conducting research where the CE has given the researcher written approval to carry out the research, the participant is an adult who has impaired capacity to consent to the research and QCAT or another person authorised under a law to make a decision for the participant consents to the person's participation (e.g., by reason of a statutory health attorney)

or

d) disclosure under section 150(a) of the HHB Act from a designated person to another designated person (the 'recipient') if the information is to be used by the recipient, acting in their capacity as a designated person, for evaluating, managing, monitoring or planning health services that are sufficiently connected to maintaining, improving, restoring or managing patient's health and wellbeing, (that is, indirect possible future connections are insufficient). The use of the authority to disclose in section 150(a) is subject to numerous caveats and conditions.

2.22. Caution should be exercised in using the authority for disclosure under section 150(a) for research and, where there is uncertainty, it should not be used (see Research Ethics and Governance Health Service Directive).

2.23. Where a researcher has a joint appointment (e.g., with the HHS and a University) there should be clarity as to the role in which the researcher is undertaking the study and seeking access to confidential information.

2.24. Advice suggests that an Opt-Out Consent Process cannot be relied upon if the legal authority relied upon is to obtain consent. A legal requirement, other than consent must be identified. e.g., an

HHB Act permission or PH Act approval or via the application of a waiver of consent identified in the appropriate section of the HREA, study protocol and approved by a HREC.

2.25. Where PH Act approval is required, a PH Act application must be completed and submitted to the PH Act administrator for consideration and approval prior to governance authorisation being granted. For more information: Access to Confidential Health Information

2.26. All research projects requesting a waiver of consent must be reviewed by an HREC. HRECs may provide a waiver of consent, in accordance with the National Statement and in the guidelines under section 2.3 (Qualifying or waiving conditions for consent).

2.27. The decision to grant the waiver of consent must be recorded in the HREC Approval letter. The Ethics Approval letter should state if the Queensland Privacy Guidelines or section 95 and 95A of the Privacy Act 1988 has been considered when granting a waiver of consent for an application.

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

- accessing potentially identifiable data from data sets,
- accessing participant records, or
- accessing identifying tissue from tissue banks.

2.28. Please refer to Queensland Health Guideline for researchers – disclosure of confidential information for detailed information.

Research involving other personal information

2.29. In addition to ethics approval, if other categories of information are relevant to the proposed research, for example, data about clinician performance, private sector health services, or general public sector service provision, then the researcher must identify a lawful authority for the use or disclosure of that information. Disclosure schemes under the Information Privacy Act 2009 may apply.

Research which has been exempt from HREC review

2.30. Unless there are exceptional circumstances, research which has been exempt from HREC review should not require governance authorisation.

Quality activities

2.31. An activity involving Queensland Health employees 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.

Clinical trials

2.32. The 'Clinical Trials' section will only appear on the SSA Form if 'Clinical Trial' has been selected in the SSA Form questions. If this question is not selected the Clinical Trials section will not appear.

Study phases

2.33. Study phases are classified by regulatory frameworks. The phase of a clinical trial is a consideration in the risk assessment of that project. Risks may be benchmarked against standard of care and using this approach the off-label use of established therapies where risks may be comparable to standard of care are taken into account. This is an alternative to adopting a strict risk categorisation corresponding to trial phase

2.34. The RGO is responsible for ensuring the insurance and indemnity arrangements are suitable in light of the risk classification / research phase of any clinical research project.

SSA for a satellite site

2.35. Under the Australian Teletrials Model, a satellite site means a site that is located in a geographically separate health facility from the primary site and responsibility is delegated by the primary site (clinical trial site) to perform activities associated with the conduct of a clinical trial and to support trial accessibility of remote participants to a clinical trial.

2.36. If the project involves a satellite site as part of a teletrial model, the name of the satellite site will be identified. For more information refer to: RGO SOP 04: Teletrials.

Clinical Trial Notification Scheme (CTN) and Clinical Trial Approval Scheme (CTA)

2.37. There are two schemes under which clinical trials involving 'unapproved' therapeutic goods may be conducted in Australia:

- Clinical Trial Notification (CTN) scheme
- Clinical Trial Approval (CTA) scheme

2.38. Clinical trials that do not involve the use of 'unapproved' therapeutic goods in humans are not subject to the requirements of the CTN and CTA schemes.

2.39. The CTN form is available online through the TGA Business Services site and only requires a Sponsor declaration.

2.40. The CTA form is submitted to the TGA when a new clinical trial involves an unregistered product or a registered product undergoing trials in a new clinical indication.

2.41. The CTA form requires sign off by the department/HHS CE or delegate. The RGO should check that the form has been signed by a representative of the Reviewing HREC and the Site PI prior to presenting it to the department /HHS CE or delegate.

2.42. It is the responsibility of the study Sponsor to ensure that all relevant approvals are in place before supplying the 'unapproved' therapeutic goods in the clinical trial.

Clinical trials registry

2.43. The World Medical Association's Declaration of Helsinki, Ethical Principles for Medical Research involving Human Subjects (2013) states that "Every research study involving human subjects must be registered in a publicly accessible database before recruitment of the first subject".

2.44. In addition, the International Committee of Medical Journal Editors (ICMJE) has stipulated in order to publish the trial results in one of their journals, the details of a trial should be publicly available in a clinical trials registry prior to recruitment of the first participant.

Examples of a publicly accessible clinical trial registry include ANZCTR or clinicaltrials.gov.

2.45. Any applicable trials in the USA must be registered and have results uploaded onto www.clinicaltrials.gov, as per section 801 of the Food and Drug Administration Amendments Act (known as FDAAA 801).

2.46. Note that DoRA 2.0 is not a World Health Organisation (WHO) compliant clinical trial registry and therefore should not be used as an answer to this question.

Insurance and indemnity

2.47. Insurance and indemnity are matters of research governance and are reviewed as part of the SSA undertaken by each institution at which the clinical trial is to be conducted.

2.48. The Sponsor of a clinical trial is an individual, company, institution or organisation which takes responsibility for the initiation, management, and/or financing of research.

2.49. This section includes guidance for insurance and indemnity for both commercial Sponsors and non-commercial Sponsors.

Site Indemnity

2.50. The level of risk of the research project will influence each HHS's decision whether or not to provide indemnity for an investigator-initiated research project, or to expect their researchers to be indemnified by a contracted party to the project. When required, the Medicines Australia Forms of Indemnity – used without amendment – are the preferred Indemnity documents.

Clinical Trials – Indemnity and Insurance

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

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

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

Commercial sponsors – Insurance and Indemnity

2.54. The Sponsor must provide indemnity to the institution and members of the Reviewing HREC against claims arising from the study per the terms and conditions set out in the relevant Medicines Australia Form of Indemnity available: Indemnity & Compensation Guidelines – Medicines Australia.

2.55. Medicines Australia, has developed two standard forms of indemnity:

1. Medicines Australia Form of Indemnity – Standard
2. Medicines Australia Form of Indemnity – HREC Review Only.

2.56. These should be used without alteration. QH does not accept any other form of indemnity without formal legal review.

2.57. The indemnities referred to above must be given by an Australian corporate entity, that is:

1. an Australian company
2. an Australian company that is a subsidiary of an overseas parent company
3. an Australian CRO that has been engaged by an overseas or Australian company to conduct the trial in Australia.

2.58. The Sponsor must provide evidence that appropriate and sufficient insurance is in place to cover these claims and should provide evidence that they are insured for clinical trials claims.

2.59. The Sponsor must comply with the Medicines Australia Guidelines for Compensation for injury Resulting from Participation in a Company-sponsored Trial, available: Indemnity & Compensation Guidelines – Medicines Australia.

2.60. The Sponsor will maintain insurance with respect to its activities and indemnity obligations under the clinical trial agreement.

2.61. This insurance is to be evidenced by a Certificate of Insurance, as requested by the institution. (A Certificate of Insurance is the document provided by an insurer or insurance broker in order to confirm the details and currency of the insurance policy). The policy must be issued by an insurer approved by the Australian Prudential Regulation Authority or an overseas insurer with a minimum credit rating of an A minus (A-) or better from Standards and Poor. The policy must remain current for the period in which the clinical trial will be conducted plus at least 7 years.

2.62. As a general guide, insurance cover should be for at least AUD $10 million per claim. The Certificate of Insurance should be up to date. The insurer insurance company (ideally) should have an Australian office or representative in this country to enable more efficient settlement of claims.

Non-commercial sponsors

2.63. Non-commercial sponsors external to Queensland Health, for example (but not limited to) research institutions, collaborative research groups (CRG) and universities have responsibility for their own indemnity.

- The non-commercial Sponsor must provide evidence of the existence of an insurance policy that covers the conduct of the clinical trial in Australia. This may be in the form of a Certificate of Insurance or if sponsored by a health department, it may be to provide details of the state self-insurance scheme.
- The non-commercial Sponsor must provide evidence of the existence of an insurance policy that is issued by an insurer approved by the Australian Prudential Regulation Authority or an overseas insurer with a minimum credit rating of an A minus (A-) or better from Standards and Poor.
- The non-commercial Sponsor must state the insurance policy will remain current for the period in which the clinical trial will be conducted plus at least 7 years.

Research agreements

2.64. RGOs are responsible for ensuring all research arrangements which involve the department and/or one or more HHSs are recorded in an appropriate contractual 'research agreement'. This includes any arrangement which involves:

- collaboration with other parties for research (e.g., collaborative research agreement)
- providing or procuring a service for research, or sharing of QH / HHS resources or facilities for research
- any use or supply of data or materials for research (e.g., Data or Material Transfer Agreements)
- confidential discussions in relation to research proposals or feasibility (e.g., Confidential Disclosure Agreements)
- publication of research findings (e.g., Authorship or Publication Agreements)
- funding for research (e.g., Funding Agreements or Grants)
- appointment of or funding for researchers (e.g., Research Fellowship Agreements).

2.65. Research agreements mitigate risks to the Queensland public sector health system and clarify the roles and responsibilities of, and allocate risks between, the parties.

2.66. While there is no mandatory form of contractual arrangement, standard terms and conditions developed through consultation between the department and the HHSs that the collaborating parties may consider for use are available on request to OPMR team.

Template research agreements

2.67. A suite of pre-agreed contract templates for various levels of projects is available. An explanation of these is in the table at Appendix 1.

2.68. The Medicines Australia template CTRAs and Medical Technology Association of Australia (MTAA) template Clinical Investigation Research Agreements (CIRA) are two examples of template research agreements which are commonly used by QH / HHSs. They describe the standard terms and conditions of conducting a study, including roles and responsibilities of stakeholders, payments, intellectual property, indemnity, insurance and compensation.

2.69. If these MA and MTAA CIRAs are used without alteration, Queensland Health will accept them without the requirement for further legal review of the agreed clauses.

2.70. If amendments to the standard terms and conditions of the Medicines Australia CTRA or MTAA CIRA are required, those amendments must be made in the appropriate schedule for 'special conditions' (e.g., Schedule 7 or Schedule 4, depending on the type of CTRA). If any changes are made to the body of a template agreement, those changes will be deemed invalid, and the original text will prevail, as per the header statement on the CTRA / CIRA.

2.71. Proposed template amendments to the Medicines Australia CTRAs and MTAA CTIAs are negotiated with the Southern and Eastern Border States (SEBS) Committee. Agreed clauses are identified with version details and are forwarded to RGOs by OPMR.

2.72. On receipt of a Medicines Australia CTRA or MTAA CIRA containing amendments in the appropriate schedule for 'special conditions', the RGO should check the version details and wording with the list of agreed clause amendments provided by OPMR. If the amendments in the CTRA / CIRA exactly match the amendments provided by OPMR, no further additional legal review of the proposed amendments is required.

2.73. If amendments to the Medicines Australia CTRA or MTAA CIRA are proposed which are not on the list for agreed amendment by OPMR, or if any amendments are proposed to any of the other template agreements listed in Appendix 1, the amendments must be reviewed by QH, an HHS lawyer or a QH approved external legal panel firm.

2.74. Irrespective of whether a template agreement requires legal review, the RGO should review the research agreement before it is referred to the department / HHS CE or delegate for signing.

Non-standard research agreements

2.75. All other non-standard research agreements not approved for use by Queensland Health e.g., other investigator-initiated research and student research contracts, must be reviewed by an HHS / the department lawyer or an approved external legal panel firm.

2.76. If the HHS does not have a lawyer or the RGO is part of the department, other Queensland Health RGO/s can be contacted to see if the research agreement has been reviewed by the department /HHS lawyer at another site.

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

2.78. After the agreement has been subject to legal review, the RGO should also review the research agreement before it is referred to the department / HHS CE or delegate for signing.

Parties to a contract

2.79. Wherever possible, the parties to a contract should be legal entities and not individuals. The parties to a contract must be properly identified to ensure the correct legal entity is bound by the research agreement. HHSs are separate legal entities and must be identified accurately in each research agreement to which they are a party. This includes the correct name, ABN and address.

2.80. External entities (including universities, research institutes or other government entities) are not considered supporting departments and are required to enter into an agreement with the department/HHS to conduct research within Queensland Health where relevant. An example of an occasion where a contract is not required is if the hospital involvement is only to assist with patient recruitment (i.e., consent to contact), then there is usually no need of any agreement unless there is a transfer of funds to reimburse staff time.

Intellectual property considerations

2.81. The RGO, in consultation with the department/HHS CE or HHS lawyer should consider whether the intellectual property arrangements for the research project are consistent with the Queensland Health Intellectual Property Policy and Standard.

Register of research agreements

2.82. RGOs should maintain a record and register of all research agreements pertaining to research to be conducted at or with any Site for which they are responsible.

Biosafety, chemical and radiation safety

2.83. Information provided by the PI / CPI (as applicable) in this section is to demonstrate to the RGO that Biosafety Committee, Drug Committee and Radiation safety approvals have been obtained if required.

2.84. Some types of research projects (such as research involving gene therapy) necessitate review and/or approval by an Institutional Biosafety Committee (IBC), Office of the Gene Technology Regulator (OGTR), the NHMRC Cellular Therapies Advisory Committee (CTAC) and the NHMRC Gene and Related Therapies Research Advisory Panel (GTRAP).

2.85. Where a project requires compliance with the ARPANSA Code of Practice for the Exposure of Humans to Ionizing Radiation for Research (2005), a medical physicist report will be required as per Section 2.1.6 which states that a PI / CPI (as applicable) must obtain an independent assessment or verification by a medical physicist. For more information: Australian Radiation Protection and Nuclear Safety Agency (ARPANSA) Code of Practice for the Exposure of Humans to Ionizing Radiation for Research (2005).

2.86. The relevant Radiation Safety Officer in the department/HHS can arrange a medical physicist to review research protocols and provide a report. They can be contacted through the local Nuclear Medicine Department.

Resources and budget information

2.87. The RGO must assess, from the information given in the governance application, which departments (main and supporting) are involved in the study and to what extent. Heads of Department/Executive Director must have been consulted and must agree to the project being undertaken in their department. Evidence of departmental support can be provided when the HoD signs the SSA Form, or a letter/email is uploaded.

Study budget at the site

2.88. The PI / CPI (as applicable) must provide a study budget to the RGO which identifies the source of funding for a proposed project and the annual or participant costs associated with the study. If there is no funding allocated to the project and the PI / CPI (as applicable) wishes to use the department /HHS staff and resources who do not normally conduct research as part of their role, free of charge, the PI / CPI (as applicable) must report the use of in-kind support and the amount (in dollar terms) from the HHS/the department site. The information provided in this section will also assist RGOs to provide data for the annual Queensland Chief Scientist report.

Site finance management

2.89. The provision of site finance management information enables the RGO to identify whether all research costs will be covered by the Sponsor and if not, how the department HHS will benefit from the non-funded research and from which cost centre those costs will be recovered.

2.90. It is the role of the HoD and Finance Managers to consider the adequacy of the local facilities nominated for proposed research and to ensure the additional time and resources spent by the researchers have been identified and are appropriate.

2.91. The RGO should consider the advice of the relevant HoD(s) and Business Manager(s) on the following:

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

Finance authorisation

2.92. Given expenditure delegates will approve expenses the signature of the local Director of Finance or delegate indicates the study budget has been reviewed and approved. This requirement is consistent with the obligations of financial management under the *Financial Accountability Act 2009* (Qld). This requirement is only for studies where the resource implications for a site are greater than AUD $10,000 because HOD(s) will be exercising financial delegation when they sign off on the application form.

2.93. For research projects with a resource budget of less than AUD $10 000 per site, PI / CPI (as applicable) Head of Department or delegate (with expenditure delegation) approval and HHS CE authorisation is sufficient for research governance approval.

2.94. Where there are resource demands for a site greater than AUD $10,000, the PI / CPI (as applicable) must discuss what the funding and resource requirements are with the department / HHS Director of Finance or delegate and cost these accordingly. The Director of Finance or delegate must sight and consider the implications of these costings before giving authorisation.

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

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

Funds management

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

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

Low risk and low-cost research

2.98. Research is 'low risk' if the only foreseeable risk is one of discomfort. If a research project involves any risk, even if unlikely, that is more serious than discomfort, the research should not be classified as 'low risk'.

2.99. A research project is classified as 'low cost' if it requires less than AUD $10,000 of monetary or in-kind support per participating site.

2.100. For a low risk and low cost multi-centre research project, principal research governance can be undertaken at a single participating HHS selected by agreement from each participating HHS.

Expedited governance process to review low risk and low-cost research

The process for expedited governance to review low risk and low-cost research includes a full SSA review by a primary RGO.

a) Primary RGO review:
    I. Full SSA review (option 1)
b) Secondary RGO review(s):
    I. SSA (option 2) submitted by local Site PI with all supporting documents.
    II. SSA sign off from local site PI's designated approver.
    III. The local site RGO is for recommendation to CE or delegate regarding authorisation.
    IV. CE or delegate decision recorded in ERM or its replacement

Note: Some projects may still require a research agreement which may need to be signed by a site.

DoRA 2.0

2.101. DoRA 2.0 is a public database that includes Queensland Health's authorised human research and is designed to facilitate greater collaboration and communication between researchers, improve community access to research information and raise awareness about the benefits of health and medical research.

2.102. DoRA 2.0 will be automatically populated from ERM. The PI / CPI (as applicable) will be asked, in the ERM forms, if they have the authority to consent for the release of the data and if so, to give consent for the release of the data.

Declarations

2.103. By signing the 'Declarations' section of the SSA Form, a PI / CPI (as applicable) or HoD is confirming that they are aware of and accept their roles and responsibilities with regards to the conduct and completion of the research project at the site.

Declarations from HoD or delegate where the research project will be conducted

2.104. The PI / CPI (as applicable) should have a signed declaration from all HoDs or service areas where resources are required to conduct a proposed research project, prior to submission of the SSA Form. This declaration is an indication that the relevant HoD(s) supports the conduct of the study in their department(s).

2.105. It is not the responsibility of the RGO to obtain the signatures of the relevant HoD(s)or Heads of Supporting Departments.

Declarations from HoD or delegate providing support and/or services to the research project

2.106. The provision of declarations from the HoD(s) or delegate providing support and/or services to a research project enables the RGO to determine under what conditions institutional departments can provide support for the research project. It is highly recommended that researchers contact the relevant supporting departments within a Site or institution (e.g., Pathology, Pharmacy, Radiology, Allied Health etc) prior to HREC submission, to ensure that any supporting services required for the research project can be provided by the nominated department(s).

3. RGO SOP 03: Processing of SSA Applications

New applications

RGO review

3.1. New applications for governance review must be submitted using ERM (or its replacement).

3.2. The RGO should acknowledge all applications within two business days of submission of the application into ERM (or its replacement).

3.3. The RGO must check that all data from the SSA Form and the supporting documents are uploaded, and that the application is complete.

3.4. It is the responsibility of the PI / CPI (as applicable) to ensure that the completed governance application contains all the essential elements when submitted to the RGO. This includes all attachments where applicable, as listed in the local RGO SSA checklist if there is one.

3.5. Site specific information should be included in the local version of the Participant Information Sheet and Consent Form (PICF) for the proposed research project, such as:

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

3.6. The research content of the PICF may not be changed by the PI / CPI (as applicable) or RGO after approval is given by the Reviewing HREC unless this is first submitted to the Reviewing HREC as an amendment and the amendment is approved by the Reviewing HREC.

3.7. The PI / CPI (as applicable) should check the footers and version details. For multi-centre research the Site Specific PICF footer should contain a reference to the Master PICF version details with additional version information inserted to identify this version of the Site Specific PICF.

3.8. Authorisation of the governance application by the department or relevant HHS CE (or their delegate) is contingent upon HREC approval of the research project and all governance requirements being met. In the parallel review process, the HREC approval letter/PH Act approval or the research agreement will be the last supporting document that the PI / CPI (as applicable) will provide.

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

3.10. The RGO must keep all documentation relating to a governance application secure and confidential and archive according to the relevant Queensland Health retention schedules.

3.11. If a mandatory supporting document has not been uploaded by the PI / CPI (as applicable), the RGO will request such further information and the PI / CPI (as applicable) must provide it before further review of the application is undertaken.

3.12. Requesting further information stops the clock. A request for information must be communicated in writing to the PI / CPI (as applicable).

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

Governance application validation

3.14. A valid governance application is one which is deemed complete by the RGO (that is, it contains all relevant signatures and supporting documentation and all RGO queries have been addressed. When the governance application is considered valid by the RGO, they change the status in ERM (or its replacement).

3.15. As a general guide, the governance application is considered valid if it meets all the following criteria:

a) all questions and sections in the SSA Form have been completed (unless prior agreement with the RGO)
b) a copy of the HREC approval letter
c) all ethics final approved documents have been attached, if requested (note if governance review is undertaken in parallel with ethics review then the HREC approval letter or the PH Act grant letter or the research agreement (if applicable) will be the final document submitted to the RGO)
d) the application has been signed by the PI / CPI (as applicable)
e) the application has been signed by supporting HoD(s)/Executive Director(s)
f) the study budget section has been completed, including details of any in-kind support to be provided by Queensland Health
g) other supporting documents (where applicable) have been electronically uploaded against the SSA Form, such as CTN, any contractual agreements, indemnity forms, biosafety/chemical and/or radiation safety approvals, and PH Act and/or QCAT approvals.

3.16. All research governance reviews exceeding 25-day clock, post validation date is monitored by the department to assess if any remedial actions are required to be implemented.

Withdrawal of applications

3.17. Applications can be withdrawn by the PI / CPI (as applicable), prior to receiving a final decision of authorised or not authorised.

3.18. Where the Site PI decides not to proceed with the research project at that site, they may withdraw the governance application. The application is withdrawn by the PI / CPI (as applicable) in ERM or its replacement

3.19. Where a PI / CPI (as applicable) has not responded to a request for further information by an RGO within three months of submission, the RGO can withdraw the application. If the PI / CPI (as applicable) still wishes to conduct the research, a new SSA application may be requested. An RGO may

make the decision to allow the PI / CPI (as applicable) to resubmit the initial SSA with the additional information.

4. RGO SOP 04: Teletrials

Sponsor Responsibilities

Clinical Trial Research Agreement:

4.1. Regardless of whether the research agreement used is the Medicines Australia (MA) Clinical Trials Research Agreement (CTRA) or another research agreement, it is the role of the Sponsor organisation to complete the agreement for the Primary Site.

4.2. The following Teletrials specific changes relate to the MA CTRA noting that they also should be incorporated into the relevant sections of any other research agreement that may be used in place of the MA CTRA, and these changes are made by the Sponsor:

- Schedule 1: agreed satellite sites should be named in Schedule 1 as participating sites in the cluster.
- Schedule 2: include agreed additional Teletrials related costs in the budget, such as extra pathology or pharmacy costs associated with shipping and retrieving pathology samples and IMP to and from satellite sites or to central laboratories.

4.3. When additional satellite sites join a cluster, the Sponsor should amend Schedules 1 and 2 of the CTRA. The primary site uses the Teletrials Subcontract to formalise its relationship (unless the satellite sites and primary sites are the same legal entity) and clinical trial activities with the satellite sites in its cluster. No contract is required between the Sponsor and any Satellite Site.

Budget

4.4. The Sponsor undertakes budget negotiations with the primary site as they would in a routine clinical trial. Reimbursement of the satellite site is a matter between the primary site and its satellite sites and is documented in the Sub-contract. Additional budget items may be negotiated by the primary site such as:

- reimbursement for costs if the primary site is responsible for sending and retrieving Investigational Products or pathology supplies/samples to and from satellite sites
- satellite site pharmacy fees if IMP is to be delivered, stored and dispensed at a satellite site
- costs associated with use of telehealth services
- outsourcing of clinical trial related assessments that may not be available at the satellite site
- costs associated with processing of source documents for monitoring purposes.

Indemnity

4.5. For commercially sponsored clinical trials, the Sponsor is required to provide indemnity to both the primary site and satellite sites, using the Medicines Australia Form of Indemnity – Standard Form (or similar).

4.6. For non-commercial clinical trials, if indemnity is provided by the Sponsor or Collaborative Group, the satellite sites should be named and individually covered. Where indemnity is not provided by the Sponsor, each participating site (primary or satellite) must hold their own insurances to conduct the trial at their site. Supervision Plans: The Sponsor is responsible for reviewing and approving supervision plans developed by the primary site in collaboration with the satellite sites in the cluster.

4.7. The Sponsor must review and approve cluster specific versions of Master documents, in the same way that the Sponsor reviews site specific versions of Master documents.

4.8. For commercially sponsored research, there will be a research governance fee for the primary site only i.e., no governance fee for satellite sites.

4.9. For non-commercial clinical trials, the primary site RGO may levy a fee, in accordance with local policies, but satellite site RGOs may not levy any fee for satellite site SSA reviews.

Primary site Responsibilities
Research Governance Requirements

4.10. The primary site undertakes research governance processes for their own site in the usual way, notifying their RGO that the trial will be conducted under the Teletrials model (if the Sponsor has already agreed to using the model), or that there is an intention to approach the Sponsor for permission to do so.

4.11. If the Sponsor has agreed, and potential participants and satellite sites have been identified, submission of documentation relating to satellite sites within the cluster should be included with the primary site's research governance application.

4.12. If satellite sites are identified after Authorisation has been granted at the primary site, notification of this amendment may be submitted to the RGO at the primary site in accordance with local processes, as soon as approval of the satellite site has received approval from the Sponsor.

4.13. The primary site must also notify the CPI of any new satellite sites joining the cluster after HREC Approval has been granted, as per the Ethics Notification section above.

Satellite Site Responsibilities
Research Governance Requirements

4.14. In collaboration with the RCCC, the satellite site prepares the satellite site Research Governance application, including:

- creation of the satellite site SSA Form

- confirmation of satellite site specific processes for participant identification, recruitment and consent
- confirmation of resources and logistics required to undertake the clinical trial at the satellite site
- confirmation of required details for the Teletrials Subcontract
- agreement on study budget and provision of relevant information required for funds transfers
- copy of the notification to the Reviewing HREC about this satellite site joining the Cluster.

4.15. The satellite site research governance application is not submitted to the satellite site RGO until after authorisation has been granted at the primary site. If the satellite site is joining the cluster sometime after authorisation has been granted at the primary site, acknowledgement of the satellite site by the primary site RGO is required for the satellite site research governance submission.

Guidance Documents

4.16. For Teletrial specific reading and documentation for RGOs:

a)	Queensland Teletrials Toolkit	Link
b)	Guidance Document for Sponsors and Sites to Establish a Teletrial	Link
c)	A Quick Guide to Establishing a Teletrial	Link
d)	Primary site RGO Submission Documents	Link
e)	Satellite site RGO Submission Documents	Link

5. RGO SOP 05: Granting institutional authorisation to conduct research

Authorisation

5.1. Once the RGO has completed the assessment of the governance application, they will provide a recommendation to the department/HHS CE or delegate.

5.2. Only the department /HHS CE or delegate can authorise a research project to commence within, or in association with, the Site(s) for which they are responsible ('institutional authorisation').

5.3. Institutional authorisation for a research project may only be given after the RGO provides a recommendation to the department / the relevant HHS CE (or their delegate) that all governance requirements have been met.

5.4. Any conflict of interest pertaining to PI / CPI (as applicable), institutions, HREC members and all other stakeholders should be considered in accordance with the Queensland Government Research

Ethics and Governance Health Service Directive as amended from time to time and the department / institutional policy.

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

5.6. The department / HHS CE or delegate may request further information from the PI / CPI (as applicable) regarding the project.

5.7. When the department/HHS CE or delegate has made the decision to authorise or not authorise the project, the RGO records the decision in ERM (or its replacement) and creates the appropriate letter of notification to the PI / CPI (as applicable).

5.8. Initial notification of the department/HHS CE or delegate authorisation to the PI / CPI (as applicable) may be via ERM, its replacement or email.

5.9. If the department/HHS CE or delegate has not authorised the commencement of the study, the RGO will inform the PI / CPI (as applicable) of the reasons and, where possible, work with the PI / CPI (as applicable) and department/HHS CE or delegate to enable the study to be undertaken, at a later date.

Guidance for potential waiving of the requirement to complete a full SSA Form

5.10. There are two separate procedures in place by which the requirement to complete a full SSA Form for each participating site may be waived (with the agreement of the RGOs at each participating site):

I. Minimum impact, minimum resource use research (e.g., hanging a recruitment poster for an HREC approved research project, but where all follow up is outside the Queensland public health system).
II. Minimum resource use research – where the total contribution from the Queensland public institution is minimal (e.g., 10-minute survey targeting six or less staff at each site).

5.11. Low risk multi-centre Research Applications which include less than AUD $10,000 of monetary or in-kind support per participating HHS may be referred by a single participating HHS selected by agreement of the participating HHSs. Subsequent research governance reviews for the project at other participating HHSs will require approval in accordance with the relevant delegations of the other HHS.

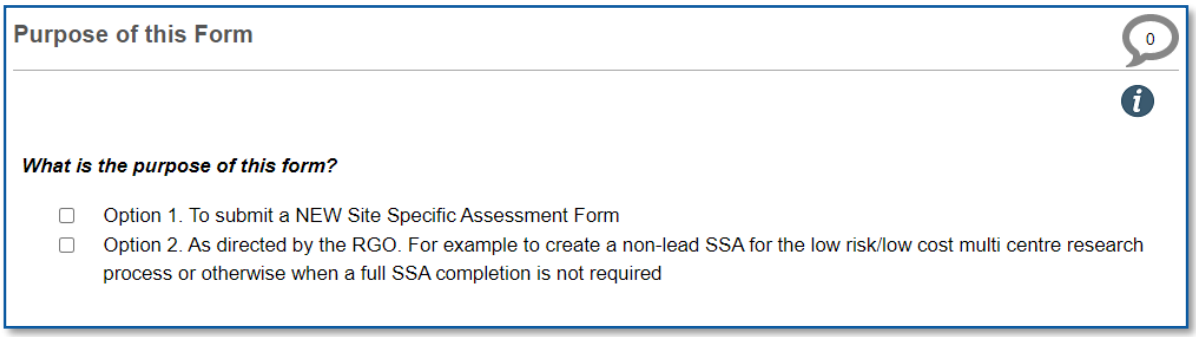
5.12. Some research projects may be eligible for consideration of a modification to the process of research governance by selection of Option 2 as the purpose of the SSA Form.

5.13. Note, the decision to waive completion of a full SSA Form (Option 1) is made by the RGO at each site, after discussion with the researcher.

5.14. Waiving of the requirement for a full SSA Form does not remove the requirement for research governance or the department/HHS CE or delegate authorisation to conduct the project.

5.15. If the SSA Option 2 is applicable, all supporting documentation is to be uploaded by the researcher.

5.16. SSA Form QLD, ERM version 2.19:



Duration of institutional authorisation

5.17. The duration of the institutional authorisation and the associated reporting requirements for the study are contingent upon the level of risk associated with the research project and are documented in the institutional authorisation letter.

5.18. The duration of the institutional authorisation should match the HREC approval timeframe (noting that some HREC approvals are extended on the basis of annual report submission).

Exceptional circumstances review

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

Exceptional Review Processing

5.20. Applications submitted for review under exceptional circumstances should contain:

a) a completed SSA Form
b) copy of the HREC approval letter
c) study protocol and supporting documentation (e.g., PICF)

d) a written request for an exceptional circumstance review, which explains the reason for requesting review and justification for the request.

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

5.22. The department /HHS CE or delegate may grant authorisation, under exceptional circumstances, for a study where:

a) a copy of the HREC approval and the application to ensure it meets the requirements of the department/institution/HHS or
b) a clinical need necessitates urgent authorisation of the application.

5.23. In some exceptional circumstance cases, the PI / CPI (as applicable) may be exempt from completing a full SSA Form (Option 1), subject to local research governance requirements. This decision will be made between the RGO and department/HHS CE or delegate and communicated to the PI / CPI (as applicable).

5.24. All authorisation documents should be signed off by the department/HHS CE or delegate in accordance with normal authorisation procedures. At this stage, the research may commence.

6. RGO SOP 06: Amendments to authorised research

Amendments to authorised research

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

Amendments to the research project which may affect the ongoing ethical acceptability of the project

6.2. Amendments approved by the Reviewing HREC must also be submitted to the relevant RGO(s) for authorisation.

6.3. The outcome of the HREC review and any revised documentation (tracked and clean copies) pertaining to the research project must be submitted by the PI / CPI (as applicable) to the relevant RGO for the department /HHS CE or delegate authorisation.

6.4. The amendment cannot be implemented at a site until site amendment authorisation has been granted.

Amendments to the research project which only affect the ongoing site acceptability of the project

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

6.6. Amendment requests for an authorised research project may be submitted directly to the RGO (bypassing the HREC) only when the amendment requires a change for example, in the following:

a) Researcher training that has been completed (including evidence of GCP training if applicable for clinical trials research)
b) anticipated start and finish dates (HREC must be told if the duration of the study exceeds the approved timeframe)
c) evidence of adequate insurance cover
d) Contract changes
e) Local departments and services involved in the research
f) Queensland Health account number(s)/cost centre details
g) finance authorisation
h) declarations and authorisations.

6.7. The RGO will determine whether authorisation from the department/HHS CE or delegate is required to implement the amendment at that site. If the RGO determines that authorisation from the department/HHS CE or delegate is not required, the RGO will notify the PI / CPI (as applicable) that the department / HHS CE or delegate authorisation is not required for the amendment to be implemented at the site.

6.8. If the RGO determines that authorisation from the department/HHS CE or delegate is required, the RGO will forward the relevant documentation to the department/HHS CE or delegate for authorisation. The RGO will then notify the PI / CPI (as applicable) as to whether authorisation has been granted.

6.9. It is the responsibility of the PI / CPI (as applicable) to ensure they have received notification of authorisation of the amendment by the RGO, prior to implementation of the amendment at that site.

6.10. If, while reviewing an amendment application from the PI / CPI (as applicable), the RGO notes that amendments to the research project may impact on the ongoing ethical acceptability of the project (for example, amendments to the recruitment process), and an amendment request has not been submitted to the Reviewing HREC, the RGO will notify the PI / CPI (as applicable) that HREC review of the amendment will be required prior to the proposed amendment being authorised and implemented at the site.

6.11. The RGO may discuss aspects of the proposed amendment with the Reviewing HREC and vice versa. For multi-centre studies approved under the single ethical review process, the local PI will notify the CPI of the requirement for ethical review by the Reviewing HREC.

6.12. The RGO will record the outcome of the amendment review in ERM or its replacement

6.13. The RGO must keep all documentation relating to the amendment for each research project in a secure and confidential manner.

Urgent safety-related measures

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

6.15. The PI / CPI (as applicable) must notify the Sponsor and RGO immediately if the protocol amendment is due to urgent safety issues at the site.

6.16. The institutions (RGOs) should comply with the NHMRC Guidance: Safety monitoring and reporting in clinical trials involving therapeutic goods November 2016.

6.17. As soon as possible, the implemented amendment should be submitted to the Reviewing HREC and RGO noting the reasons for implementation of the change prior to review/approval and obtain the HREC approval and RGO authorisation in the normal way.

7. RGO SOP 07: Monitoring of research that has been given Departmental/HHS authorisation

Monitoring of research

7.1. Every site where research is conducted has ultimate responsibility for ensuring, via its research governance arrangements, that all of its approved research is monitored.

7.2. In the case of Commercially sponsored research, generally the sponsor will take on the responsibility of monitoring.

7.3. For non-commercially sponsored research, monitoring will be coordinated via the site's research governance office.

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

7.5. Participating sites must have a mechanism for the review of SAEs occurring at their institution, which is external to and separate from the Reviewing HREC.

7.6. RGOs should have mechanisms such as site auditing which would include the review of reports that the HREC has received to determine whether any changes should be made regarding the site specific assessment of a study

When the institution takes on the role of the Sponsor

7.7. The Reviewing HREC states in the HREC Approval letter the frequency, type and format of reporting and monitoring which reflects the degree of risk of the research.

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

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

7.10. On-site monitoring, coordinated by the Research office, may include:

a) auditing/inspection of research conducted in compliance with the agreed protocol and conditions of approval, including consent documentation, current number of participants, commencement/completion/withdrawal dates
b) auditing/inspection of research conducted in accordance with ICH GCP
c) auditing/inspection of data storage and security.

Reporting to the RGO

Commencement report

7.11. Notification of the study start, if required should be made by the PI / CPI (as applicable) to the RGO within 30 calendar days of study commencement.

7.12. The RGO may record the study start date using the custom data fields in ERM.

Progress reports

7.13. PI / CPI (as applicable) is required to report at least annually to the RGO on matters including:

a) progress reports to date or final reports in the case of completed research
b) maintenance and security of records
c) compliance with the approved protocol
d) compliance with any conditions of approval.

Clinical trials

7.14. A safety report is a requirement of the NHMRC's Safety monitoring and reporting in clinical trials involving therapeutic goods. The PI / CPI (as applicable) or delegate is responsible for monitoring the safety of their research project(s) and preparing a safety report.

7.15. The safety report should be submitted to the Reviewing HREC. Once the Reviewing HREC response is obtained, the PI / CPI (as applicable) should submit this, along with the annual report and supporting documentation, to the relevant RGO.

7.16. Individual line listings of Adverse Events are not required when submitting a safety report.

7.17. The PI or delegate are required to monitor the safety of a clinical trial at a site under their jurisdiction and act upon information which may impact on the institution's duty of care to patients and clinical trial participants at that site.

7.18. Monitoring is achieved by assessing whether safety events that occur at a site impact on the medico-legal risk, responsible conduct of research or contractual obligations. RGOs must acknowledge the receipt of this communication, and where appropriate, act on this information to facilitate corrective and preventative action.

Information that sponsors are to provide to the institution/RGO

7.19. A significant safety issue (SSI) that meet the definition of an 'urgent safety measure' (i.e., a measure required to be taken immediately in order to eliminate an immediate hazard to a participant's health or safety) must be reported by the Sponsor to the institution/RGO within 72 hours of becoming aware of the event.

7.20. Suspected Unexpected Serious Adverse Reactions reports (SUSARs) arising from the local site or any other information received by the sponsor that may be new and have an impact on the continued ethical acceptability of a research project or may indicate the need for Amendments to the research protocol (including additional monitoring of safety), must be reported by the Sponsor to each relevant site RGO within 72 hours of becoming aware of the event.

7.21. The Sponsor of a clinical trial / research project must also provide an Annual Safety Report/ Development Safety Update Report to each relevant site RGO as necessary.

Suspension or withdrawal of HREC Approval

7.22. Where the Reviewing HREC suspends or discontinues ethics approval for a study, the PI / CPI (as applicable) must immediately (within 24 hours of becoming aware of the HREC decision) notify the relevant RGO(s).

7.23. The RGO(s) will immediately note the suspension/withdrawal in ERM (or its replacement) by updating the project status and notify in writing to the PI / CPI (as applicable) their acknowledgment of the suspension or withdrawal at the site.

Suspension or withdrawal of site authorisation

7.24. Where the department/HHS CE or delegate is satisfied that circumstances have arisen where it is no longer appropriate to conduct a research project at one or more sites/HHS, the department/HHS CE or delegate may suspend or withdraw authorisation to conduct the research at those sites.

7.25. In such circumstances, the RGO is required to immediately notify both the Reviewing HREC and the PI / CPI (as applicable).

7.26. In some cases, the RGO may consult with the Reviewing HREC first, to ensure the safety and welfare of research participants that may be involved in the research. It is recommended the notification be confirmed in writing within three business days and it is the responsibility of the RGO to update the project status ERM (or its replacement). In some instances, an institution can suspend the study before consulting with the reviewing HREC for example retrospective studies where the PH Act approval has been breached.

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

7.28. A Site PI cannot continue with a research project if the department/HHS CE or delegate has suspended or withdrawn authorisation for the research to be conducted at that site.

Study closure/termination at a site

7.29. Where an authorised research project is to be closed at a site, the PI / CPI (as applicable)must notify the Reviewing HREC. The PI / CPI (as applicable) will also be required to notify the RGO.

7.30. Where a research project at a site is prematurely terminated by the PI / CPI (as applicable), the HREC and RGO should be promptly informed and provided with a detailed written explanation of the circumstances.

7.31. The project status in ERM (or its replacement) should be updated accordingly by both the HREC Administrator and RGO once notified of study closure/termination.

8. RGO SOP 08: Fees for governance review

Schedule of fees

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

8.2 Fees may also be levied by Queensland Health to recover costs associated with ethics review and monitoring of research projects from PI / CPI (as applicable) external to Queensland Health.

Note, RGO review fees will be exempted by Queensland Health for satellite site governance review under the Teletrial model.

Payment of fees

8.3 It is the responsibility of the PI / CPI (as applicable) to provide the RGO with details of the sponsor or CRO to whom the invoice will be sent.

8.4 Invoices will be sent to the Sponsor (or CRO acting for the Sponsor) by the department/site/HHS Finance Department as per local business practice.

8.5 The department/HHS CE or delegate may withhold final research authorisation or suspend authorisation (as appropriate) until the invoice has been paid.

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

9. RGO SOP 09: Handling complaints

General guidance

9.1 NHMRC Guide to Managing and Investigating Potential Breaches of the Australian Code for the Responsible Conduct of Research (2018) sets out a framework for managing and investigating potential breaches of the 2018 Code which, for many institutions, will operate separately from and prior to other institutional processes. However, institutions need to consider the legal framework within which they are operating as processes established in workplace and student disciplinary agreements may prevail over the guidance in this document.

9.2 Sites / institutions need to identify and clearly document the roles and responsibilities of those involved in the management and investigation of potential breaches of the 2018 Code and should indemnify individuals involved in the investigation process appropriately.

9.3 Sites / institutions are required to manage concerns or complaints and investigate potential breaches of the 2018 Code related to research for which they are responsible.

9.4 Sites / institutions must make public the process for receiving and resolving allegations of breaches of the Code. This should be consistent with the 2018 Code and:

- NHMRC Guide to Managing and Investigating Potential Breaches of the Australian Code for the Responsible Conduct of Research (2018) — Link
- Queensland Health Requirements for reporting suspected corrupt conduct E9 Policy QH-POL-218 (2019) — Link

For more information, please refer to: Research Complaints Procedure – Queensland Health

Institutional responsibilities

9.5 Any concern, allegations or complaints about the conduct of a project must be reported in the first instance to the Reviewing HREC, and the Site / institution's designated person for handling research complaints, including research misconduct.

9.6 For more information, please refer to the Queensland Health Ethical Standards Unit.

9.7 Any complaints received must also be forwarded to the HREC Administrator of the Reviewing HREC who will record the complaint details, and to the Site RGO where the complaint applies, as well as with the department if a PH Act has been granted.

9.8 As per the 2018 Code and NHMRC Guide to Managing and Investigating Potential Breaches of the Australian Code for the Responsible Conduct of Research (2018) the department or relevant HHS(s) CE (or their delegate) will nominate advisers in research integrity to advise possible complainants about research conduct issues and explain the options open to persons considering making or having made an allegation.

9.9 Institutions should consider how preliminary assessments and investigations into potential breaches of the 2018 Code are to be conducted, including for multi-institutional collaborations on a case-by-case basis, taking into consideration issues such as the lead institution, where the complaint was lodged, contractual arrangements or where the events occurred. RGOs should consult with the relevant Site / institution personnel to become familiar with these procedures although they are not responsible for developing and/or implement them

9.10 Sites / institutions should cooperate if there is a potential breach of the 2018 Code to ensure that only one investigation is conducted. There should be clear communication between all parties throughout the investigation.

9.11 The department / HHS CE will nominate a Designated Officer (DO) for handling research complaints, including research misconduct. Any concern, allegations or complaints about the conduct of a project must be reported, in the first instance, to the institution's DO.

9.12 Where a complainant chooses not to proceed with a complaint, the Site / institution still has an obligation to assess the nature of the complaint and whether to proceed to a preliminary assessment.

9.13 The DO determines whether the complaint relates to a potential breach of the 2018 Code and, if it does, the matter proceeds to preliminary assessment.

9.14 If the matter proceeds to a preliminary assessment, the DO assigns the complaint to a suitable Assessment Officer (AO). The AO is responsible for the conduct of the preliminary assessment,

ensures timeliness and consults with the DO, as required. The AO should ensure records of the preliminary assessment are prepared and retained, and that appropriate processes are followed. On completion of the preliminary assessment, the AO provides written advice to the DO in a timely manner. This should include:

a) a summary of the process that was undertaken
b) an inventory of the facts and information that was gathered and analysed
c) an evaluation of facts and information
d) how the potential breach relates to the principles and responsibilities of the 2018 Code and/or institutional processes and recommendations for further action.

The preliminary assessment advice will be considered by the DO who determines, on the basis of the facts and information presented, whether the matter should be:

a) dismissed
b) resolved locally with or without corrective actions
c) referred for investigation
or
d) referred to other institutional processes.

9.15 The institution should provide the outcomes, if appropriate, to the respondent and complainant at the conclusion of a preliminary assessment in a timely manner.

9.16 If the DO determines an investigation is required, the following steps will be taken:

a) investigation Panel prepare a clear statement of allegations
b) nominate the investigation Panel (Panel) and Chair when the Panel is more than one person
c) seek legal advice on matters of process where appropriate.

9.17 The Panel completes an investigation into the potential breach into the 2018 Code and reports its findings and recommendations.

9.18 The findings of the investigation should include recommendations about other institutions/organisations that should be advised of the outcome (for example, funders, external stakeholders).

9.19 The department / HHS CE decides on further action which may include corrective actions, referral to an institution's disciplinary processes and/or other institutional processes.

Procedure for handling complaints concerning the governance review process, including refusal of an application.

9.20 The PI / CPI (as applicable) may appeal the research governance review decision of the department/HHS CE or delegate.

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

9.22 The RGO will notify the department/HHS CE or delegate of any complaints received as soon as possible. The department/HHS CE or delegate will inform the RGO of any complaints received directly by them (not the RGO) as soon as possible.

9.23 The RGO will investigate the complaint and its validity and make a recommendation to the department/HHS CE or delegate on the appropriate course of action.

9.24 The RGO will provide to the department/HHS CE or delegate all relevant information about the complaint/concern.

9.25 The department/HHS CE or delegate will make the final determination regarding the complaint and will either:

a) uphold the complaint and authorise the study *or*
b) provide further justification to the Site PI why the study has not been authorised.

10. RGO SOP 10: Archiving, storage and retention of RGO records and documentation

Archiving completed studies

10.1. Once a study has been completed and the project status is Closed and Archived, the project and all accompanying documentation may be removed from the Research Governance Office and archived according to Queensland Health record retention policy.

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

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

Appendix 1 - Pre-agreed contracts for projects explanatory table

Name of agreement	Situation for use	Available from

Medicines Australia Clinical Trial Research Agreement (CTRA) – Standard Form	Used for commercially sponsored phase 0-IV clinical trials where the Sponsor undertakes all responsibilities for the conduct and ongoing management of the project.	Medicines Australia website: Clinical Trial Research Agreements – Medicines Australia
Medicines Australia CTRA – CRO	Used for commercially sponsored phase 0-IV clinical trials where a CRO has been engaged to manage the study in Australia.	Medicines Australia website: Clinical Trial Research Agreements – Medicines Australia
Medicines Australia CTRA Observational/Phase IV studies	Used for commercially sponsored observational or phase IV studies.	Medicines Australia website: Clinical Trial Research Agreements – Medicines Australia
Medicines Australia CTRA - CRG	Used for clinical trials that are not commercially sponsored, being undertaken by CRGs (investigator-initiated).	Medicines Australia website: Clinical Trial Research Agreements – Medicines Australia
Medical Technology Association of Australia (MTAA) Standard CIRA	Used for sponsored clinical investigations involving new technologies.	MTAA website: Clinical Investigation Research Agreements - MTAA
Clinical Trial Research Agreement Subcontract for Studies Conducted under a Teletrial Model	Used for clinical trials conducted under the Tele-trials model.	Tele-Trials – Medicines Australia

Health Translation Queensland (HTQ) Research Passport Agreement	The HTQ Research Passport Agreement is a collaborative agreement designed to streamline research collaboration between HTQ Partners through the use of agreed legal terms. It consists of an umbrella agreement and an operating schedule. Please note it cannot be used for Clinical Trials. For information, please go to the HTQ website.	Research Passport Agreement
Multi-Jurisdictional Multi-Party Non-Clinical Trials Collaborative Research Agreement	National, Non Compulsory Agreement endorsed by the Clinical Trials Project Reference Group (CTPRG) in April 2022	For information, please go to the CTPRG website.
QH Public Health and Forensic Science Multiparty Collaborative Research Agreement (CRA)	This agreement is to be used when: a) QH **engages in research** activities; and b) QH personnel **make an**	FSS Research Office FSS_Research@health.qld.gov.au

	intellectual, creative or inventive contribution to the research project	