# Standard Operating Procedures

## For Queensland Health Human Research Ethics Committee (HREC) Administrators

Queensland Government

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Amendment history

| Version | Date | Author/s | Amendment details |
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| 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 |
| 7.0 | October 2024 | ORI | Reflect OPMR change of name to ORI and move to CPSS. Reflect updates to the National Statement 2023 and inclusion of external research promotion guidelines |

Standard Operating Procedures for Queensland Health Human Research Ethics Committee (HREC) Administrators.

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# Acknowledgements

These Standard Operating Procedures (SOPs) have been developed by the Office of Research and Innovation (ORI), Clinical Planning and Service Strategy 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

Human Research Ethics Review is a process to explore the ethical issues presented by, and implications of, a research project involving humans. Human Research Ethics Committees (HRECs) play a central role in the Australian system of ethical oversight of research. HRECs review research proposals involving human participants to ensure that they are ethically acceptable, have scientific merit, protect the rights, safety and privacy of participants and are beneficial and just in accordance with relevant standards and guidelines, including the National Statement on Ethical Conduct in Human Research 2007 (Updated 2018) (National Statement).

The purpose of this document is to provide standard operating procedures (SOPs) for Queensland Health HRECs and HREC Administrators. The SOPs are designed to assist the department and Hospital and Health Services (HHSs) to ensure that their HRECs are constituted and operate in accordance with the National Statement and the National Health and Medical Research Council (NHMRC) Australian Code for the Responsible Conduct of Research, 2018 (the 2018 Code).

These SOPs promote compliance with nationally accepted guidelines for ethical review of human research. The related governing legislation, policy and agreements referred to in this document outline Queensland Health's responsibilities for the conduct of research within the department and HHSs which are consistent with the following regulatory and guidance documents listed below, as updated from time to time.

Reference documents:

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| • NHMRC National Statement on Ethical Conduct in Human Research 2023 | 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) |

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| • *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-013:2022**) | 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 | |
| • Queensland Health Research Ethics and Governance Health Service Directive QH-HSD-035 | Link | |

# Scope

The SOPs apply to human research undergoing review by a Queensland Health HREC.

# Implementation

These SOPs outline the minimum Queensland Health HREC standard administrative processes when carrying out the ethical review of human research.

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

Queensland Health administrators will direct researchers to submit research applications, and all required supporting documentation using Ethics Review Manager (ERM) or its replacement.

Researchers should submit research applications using the Human Research Ethics Application (HREA) noting there are two HREA templates –

i) NHMRC HREA accessed through the NHMRC portal
ii) Ethics Review Manager (ERM) HREA accessed through the ERM website

Both versions of the HREA are acceptable - they ask the same questions however are supported by independent IT platforms. The NHMRC HREA must be imported into ERM by the researcher for processing by the Queensland Health HREC.

# Definitions and abbreviations

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| **Adverse event (AE)** | **Investigational Medicinal Product (IMP) Trials**<br>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**<br>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.<br><br>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. |

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| **Adverse event (AE)** | An incident in which unintended harm resulted to a person involved health care research. May include non-interventional research.<br><br>(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:<br>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:<br>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.<br>Synonymous with Site Coordinator, Clinical Study Coordinator, Clinical Trial Coordinator, Research Nurse. |

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| **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.<br>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.<br>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. |

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| **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:<br>• Researcher Portal used by researchers to submit a HREC or RGO application, amendments and reports for HREC or RGO review and approval.<br>• Administrators Portal used by HREC members/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:<br>• https://www.tga.gov.au/publication/note-guidance-good-clinical-practice |
| **Office of Research and Innovation** | The Office of Research and Innovation (ORI) is responsible for consultation, development and review of State-wide research ethics and research governance policies. ORI 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. ORI was formally known as Health Innovation, Investment and Research Office (HIIRO). Contact our research office \| Queensland Health |
| ***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. |

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| **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.<br>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.<br>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 the HREC. |
| **Identifier** | Details attached to data such as name, image, date of birth or address, attribute or group affiliation, from which and/or contact information that identify an individual. |
| **Lower Risk Research** | Research where there is no risk of harm, the only foreseeable risk is one of discomfort; potential for minor burden or inconvenience. Where the risk, even if unlikely, is more serious than discomfort, the research is not lower risk.<br>National Statement on Ethical Conduct in Human Research 2023 \| NHMRC |

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| **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 a certified 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 2023 (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:<br>National Statement on Ethical Conduct in Human Research 2023 \| NHMRC |
| **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:<br>National Statement on Ethical Conduct in Human Research 2023 \| NHMRC |
| **Personal Information**<br>**(as per *Information Privacy Act 2009*)** | In accordance with the *Information Privacy Act 2009* (Qld)<br><br>Personal information is information or an opinion, including information or an opinion forming part of a database, whether true or not, and whether recorded in a material form or not, about an individual whose identity is apparent, or can reasonably be ascertained, from the information or opinion. |
| ***Public Health Act 2005* (PHA)** | The *Public Health Act 2005* (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. |

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| **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.<br><br>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 (QA) Activity** | 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<br><br>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 the Office of Research and Innovation and encompasses the former Research Ethics and Governance Unit of the Office Health Medical Research (OHMR). |
| **Queensland Health (QH)** | 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. |

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| **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:<br>• assessing the site specific aspects of research applications<br>• making recommendations to department/HHS CE or delegate as to whether a research study should be granted authorisation at that site<br>• 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 of a proposed research project based on information provided in the site – specific application form . 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 site -specific assessment 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:<br>NHMRC Safety monitoring and reporting in clinical trials involving therapeutic goods |

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| **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). Examples would be changes to site contracts and changes to participating site staff other than the PI. |
| **Site Start Date** | Refers to either the anticipated first point of recruitment (i.e. the date when the advertising or screening for participants begins) or start of data collection. |
| **Sixty (60)-day clock** | The period of 60 clock days allowed for scientific and ethical review, decision making by a Certified HREC. For research not requiring review at a full HREC meeting, the clock starts on receipt of a valid application. For research requiring review at a full HREC meeting the clock starts on the relevant HREC meeting closing date. The 60-day time limit excludes stop clock days. |
| **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 Northern 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. |

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| **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.<br><br>'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.<br><br>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:<br>NHMRC Safety monitoring and reporting in clinical trials involving therapeutic goods |
| **Teletrial** | A teletrial uses telehealth technology to communicate between the Primary Site and Satellite Site/s and enable delivery of aspects of a clinical trial as defined in the Supervision Plan. This technology supports a Principal Investigator to supervise Associate Investigator/s to conduct a clinical trial at a Satellite Site which is geographically remote from the Principal Investigator's Primary Site. The Principal Investigator remains responsible for the trial. |
| **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/ |

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| ***Transplantation and Anatomy Act 1979*** | The *Transplantation and Anatomy Act 1979* 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. |
| **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 HREC Administrator to verify that all applicable documents are submitted prior to review. |
| **Validation date** | For research not requiring review at a full HREC meeting, the date on which a valid application is received by a HREC Administrator. For research requiring review at a full HREC meeting, it is the relevant HREC meeting closing date. |

# 1. HREC 001: QLD Health HRECs

## 1.1. Objectives

The objectives of the HREC are to:

- Protect the mental and physical welfare, rights, dignity and safety of participants of research.
- Promote ethical principles in human research.
- Review research in accordance with the National Statement; and
- Facilitate ethical research through efficient and effective review processes.

## 1.2. Functions

The HREC functions on behalf of the department/HHS are to:

- Provide independent oversight of human research projects.
- Provide competent, timely review and monitoring of human research projects in respect of their ethical and scientific acceptability for as long as projects are active.
- Determine the compliance of a human research project with the National Statement and grant, withhold or withdraw ethics approval and;
- Provide advice to the department/HHS on strategies to promote awareness of the ethical conduct of human research.

## 1.3. Accountability

The HREC is directly accountable to the department or HHS under which it is constituted.

Failure to comply with the requirements of the National Statement may result in the HREC being removed from the list of HRECs registered with NHMRC.
For more information refer to: National Statement, Establishment of HRECs

The minutes of each HREC meeting are forwarded to the Chief Executive or nominated delegate following confirmation or according to the local HREC Terms of Reference.

The HREC provides an annual report to the Chief Executive or nominated delegate at the end of each financial or calendar year. The Executive of the Authority (the department/HHS CE/delegate) should be provided with an annual report which contains details of applications made to the HREC and any other requested information required for HHS/institutional reporting.

The HREC brings to the attention of the Chief Executive or nominated delegate issues of significant concern. The HREC provides the following reports on behalf of the department/HHS to the relevant body:

- Australian Health Ethics Committee (AHEC) report in accordance with the requirements of the NHMRC.
- For certified institutions only, Certified Institution Annual Report to the National Health and Medical Research Council (NHMRC).
- Monitoring Measures: The HREC will undertake its review in a timely and efficient manner and have mechanisms to monitor and evaluate its performance.

- Any other reports required.

## 1.4. Application Review

**1.4.1.** Single-centre research applications

The HREC provides ethical and scientific review of single-centre research at sites within or outside its jurisdiction.

**1.4.2.** Multi-centre Research Applications

The reviewing HRECs provide ethical and scientific review of multi-centre research applications on behalf of the Queensland public health system. A publicly funded health organisation within a participating jurisdiction is able to accept the scientific and ethical review of a Queensland Health NHMRC certified reviewing HREC for a multi-centre research project.

**1.4.3.** Ethical and scientific review for external entities.

The HREC reviews human research applications for external institutions/organisations and investigators as approved by the Chief Executive of the institution responsible for the HREC. Provision of ethical and scientific approval to an external entity is conditional upon the execution of an agreement which specifies the respective legal responsibilities and liabilities for the HREC and the external entity.

(For certified institutions only) The HREC may review applications from interstate institutions or organisations within the scope of a scheme of mutual acceptance of ethical and scientific review entered into by Queensland Health on behalf of the HREC and documented in a Memorandum of Understanding.

## 1.5. Role of the HREC Chair

The HREC Chair is responsible for the conduct of HREC business and for ensuring that the HREC reaches decisions on all matters. Where the HREC Chair is unavailable for a HREC meeting, it will be chaired by the Deputy HREC Chair.

## 1.6. Role of the HREC Executive Committee

Each HREC may have an Executive Committee comprising of at least the HREC Chair/delegate and a member of the department or relevant HHS/institution/facility research office.

The HREC Executive Committee is delegated to undertake expedited review and approval of business that does not require full HREC review, including some or all of the following:

a) Lower risk research applications.
b) Amendments to current HREC approved projects.
c) Responses to HREC queries, as approved by the full HREC for HREC Executive Committee review and approval.
d) Annual progress reports and0020final reports and
e) Serious adverse events and suspected unexpected serious adverse reactions reports.
f) Quality assurance activity

The minutes of HREC Executive Committee meetings and decisions of the HREC Executive Committee are noted at the next HREC meeting.

**1.7.** The HREC Chair has the discretion to delegate to HREC administration officers the authority to undertake review of HREC Executive Committee business that is considered administrative or within the capacity of the delegate such as:

a) Amendments to Participant Information Sheets and Consent Forms that address changes requested by the HREC and require little interpretation of the ethical impact of the amendments. Changes include standard statements regarding insurance/indemnity, contact details, version control, dates, etc.

b) Amendments to other study documents (e.g., case report forms, patient diaries) that are administrative in nature or of low ethical risk.

c) Changes to project personnel and

d) Other issues, on a case-by-case basis, such as responses to HREC queries and annual progress reports and final reports.

**1.8.** **Role of the HREC Subcommittees**

HREC subcommittees are appointed to carry out scientific or technical review of applications. The Chairperson of a subcommittee is appointed by the department/HHS Chief Executive. Members of the subcommittee need not be members of the HREC and are appointed by the subcommittee Chairperson.

The minutes of the subcommittee meetings are noted at the next HREC meeting.

**1.9.** **Role of the HREC Administrator**

The secretary to the HREC meeting will be the HREC Administrator (or their delegate).

**1.9.1.** The responsibilities of the HREC Administrator in relation to HREC meetings include but are not limited to the following activities:

a) Publishing the schedule of HREC meetings.
b) Preparing the agenda.
c) Allocating lead reviewer(s) - in conjunction with the HREC Chair (where this is the practice of the HREC).
d) Distributing the agenda and papers.
e) Inviting PIs and, where appropriate, supervisors to attend the meeting and making the necessary arrangements.
f) Preparing the venue.
g) Recording apologies for absence prior to the meeting.
h) Raising with the HREC Chair any concern that a meeting may not be quorate.
i) Recording attendance by HREC members and reviewers of each application for ethics review.
j) Advising the HREC as necessary on compliance with SOPs.
k) Taking and preparing the minutes of the meeting for review and approval by the HREC Chair.

l) Notifying applicants of decisions given at the meeting (within four working days) and attending to other follow-up action as necessary.
m) Organising for the department/HHS CE/delegate to sign 'Form of Indemnity – HREC Review Only' where necessary, and
n) Completing the NHMRC Annual Report to maintain the registration of the HREC for final sign-off and approval by the HREC Chair/HHS CE (or their delegate).

**1.10.** **Information about HRECs**

The department/HHSs ensure the following information about their HREC(s) is publicly available:

a) HREC contact details.
b) Submission closing dates for HREC meetings (and scientific/technical subcommittees if applicable).
c) HREC meeting dates.
d) The specific area of research the lead HREC is accredited to review (i.e., clinical research, general research) and
e) The sites within their jurisdiction for ethical and scientific review.

**1.11.** Queensland Health ensures that the name and contact details of Queensland Health HRECs are publicly available on the Queensland Health external website.

**1.12.** Where the HREC is to be merged, closed or has ceased to function, the HHS (as applicable) notifies the NHMRC and determines the appropriate course of action, such as the status of its registration and/or status as a certified institution with the NHMRC and the monitoring of previously approved research. The HHS (as applicable) also notifies ORIwithin Queensland Health.

# 2. HREC 002: HREC composition

**2.1.** The minimum membership for meetings of a HREC is specified in the National Statement. In summary, a HREC must be comprised of:

- one Chair
- two people who bring a broader community or consumer perspective and who have no paid affiliation with the institution at least one person with knowledge of, and current experience in, the professional care, counselling or treatment of people
- at least one person who performs a pastoral care role in the community
- at least one lawyer (where possible one who is not engaged to advise the institution) and
- at least two people with current research experience that is relevant to the research proposals to be considered at the meetings they attend.

As far as possible, it should be ensured each meeting has diversity, including gender diversity with at least one third of the members from outside the institution for which the HREC is reviewing research.

**2.2.** The lawyer on the HREC participates in the ethical review of the study and does not provide legal advice to the HREC or the researchers on research-related or any other matters.

**2.3.** HRECs that review research about Aboriginal and Torres Strait Islander people or communities should appoint one or more members who have knowledge of research with Aboriginal and Torres Strait Islander Peoples or relevant cultural knowledge. The appropriate qualifications of individuals being considered for appointment as a member in this category should be considered by the relevant Aboriginal and Torres Strait Islander communities.

**2.4.** HRECs are encouraged to establish a pool of inducted members, across all of the categories specified in the National Statement. Additional members may attend meetings as needed to meet minimum HREC requirements (a quorum) and may also be available to provide expertise for the research under review.

**2.5.** Where there is less than full attendance of the minimum membership at a HREC meeting, the meeting may proceed provided the HREC Chair is satisfied that the views of those absent who belong to the minimum membership have been received and considered, and that absent members who have not provided comment have had the opportunity to provide comment by being provided with the agenda papers. The HREC Administrator should present all comments/views submitted by absent members as appropriate during the HREC meeting. Absent members comments against an application should be noted in the minutes as being considered.

**2.6.** Otherwise, if a quorum has not been satisfied, the HREC may not commence, continue or conclude any discussion with the purpose of determining the HREC's decision on an application for ethics review. However, the HREC may proceed with any other business on the agenda as if it were a sub-committee meeting, provided that the HREC Chair (or Deputy Chair)) and at least one other HREC member is present.

**2.7.** The HREC Administrator should keep a record of attendance, indicating which HREC members were present, which members were absent and provided comment, and which members identified a conflict of interest against any of the items of discussion at the meeting.

**2.8.** Where a HREC member states a conflict of interest that requires their absence for the consideration and decision making for an application, the quorum requirements must still be upheld.

**2.9.** The HREC Administrator should indicate when section 95 or 95A of the *Privacy Act 1988* or if applicable, the Queensland Privacy Guidelines (under development) are considered against an application by the HREC and the decision made concerning the application for a waiver of consent.

**2.10.** The roles and responsibilities required of HRECs under the *Therapeutic Goods Act 1989* can be found at: Clinical trials | Therapeutic Goods Administration (TGA).

# 3. HREC 003: Appointment of members

**3.1.** The National Statement provide guidance on recruitment of HREC members.

**3.2.** The institution is to recruit members for a HREC using open and transparent processes.

**3.3.** Advertisements may be placed, seeking members for a HREC, or potential members may be referred to the HREC.

**3.4.** Normal background checks, as applicable to the institution, will be undertaken for applicants external to the institution.

**3.5.** HREC members are to be appointed for their expertise and knowledge and not in a representative capacity of any organisation, group or opinion.

**3.6.** HREC members are not to be appointed in more than one of the categories listed in the National Statement.

**3.7.** A HREC may establish a pool of appointed members in each category. It is recommended that the HREC is comprised of at least 12-15 members to account for absences and to provide the Committee with a wide range of professional backgrounds.

**3.8.** Institutions should review appointments to the HREC at least every three years.

**3.9.** Appointed members must receive a formal notice of appointment (including the terms of appointment) and assurances that the institution or organisation will provide legal protection in respect of liabilities that may arise in the course of bona fide conduct of their duties as HREC members.

**3.10.** Membership of the HREC (not including actual members names) and Terms of Reference (ToR) should be made available to the public via an annual report or by other routine processes.

**3.11.** Members are appointed for a period of up to three years and may serve a total of six years (two consecutive terms) unless otherwise approved by the HHS CE or delegate.

**3.12.** The Chief Executive or delegate, in consultation with the HREC Chairperson, may implement a probationary period. Noting there may be local TOR and SOPs that have other time frames.

**3.13.** The HREC Chair, Deputy Chair and Chair of any subcommittee may serve longer terms with the approval of the Chief Executive or delegate. Members are advised when their term is due to expire. Reappointment is by application to the Chairperson of the HREC who then makes a recommendation to the Chief Executive or delegate.

**3.14.** New and renewed appointments allow for continuity, development of expertise within the HREC, and regular input of fresh ideas and approaches.

**3.15.** All HREC members must sign a conflict of interest declaration annually, which will be maintained on the members personnel file.

**3.16.** HREC membership lapses if a member fails to attend:

- Three consecutive HREC meetings without reasonable excuse/apology or exceptional circumstances; and
- At least two thirds of all scheduled HREC meetings in each year, barring exceptional circumstances.

**3.17.** The HREC Chair must notify the member of a lapsed of membership in writing and coordinate steps to fill the vacancy.

**3.18.** Members seeking to resign or take a leave of absence for an extended period from the HREC are asked to give notice to the HREC Chair and the HREC Chair will coordinate steps to fill the vacancy.

**3.19.** The appointment of any member of the HREC may be terminated if the Chief Executive or their delegate is of the opinion that:

- it is necessary for the proper and effective functioning of the HREC
- the member is not a fit and proper person to serve on an HREC or
- the member has failed to carry out their duties as an HREC member.

**3.20.** HREC members are expected to participate in relevant specialised working groups as required.

**3.21.** The HREC Chair is expected to be available between meetings to participate in HREC Executive Committee meetings where required.

**3.22.** The department/HHS provides indemnity for members of the HREC liabilities that arise as a result of the member exercising their duties in good faith. Such indemnity is provided through the Queensland Government Insurance Fund.

**Optional Reimbursement of expenses for HREC members**

**3.23.** It is the responsibility of the HREC Administrator to ensure that HREC members' legitimate expenses are reimbursed without delay.

**3.24.** Reasonable expenses incurred travelling to and from HREC meetings will be reimbursed.

**3.25.** An original receipt is required before any HREC expenses will be reimbursed.

**3.26.** A Petty Cash Voucher and Staff Expense Claim should be completed or otherwise comply with local procedures.

# 4. HREC 004: Orientation and training of members

**Education and training**

**4.1.** New HREC members are provided with appropriate induction, orientation and training as determined by the Department and HHS.

**4.2.** This includes provision of and training on the National Statement, the 2018 Code, HREC Terms of Reference, their responsibilities and HREC meeting dates.

**4.3.** Induction should also include mentoring by a current HREC member and continuing education.

**4.4.** Orientation may involve some or all of the following but not limited to:

a) Introduction to other HREC members prior to the HREC meeting.
b) Provision of an orientation package.
c) Informal meeting with the HREC Chair and Executive Officer to explain their responsibilities as an HREC member, the HREC processes and procedures.
d) 'Partnering' with another HREC member in the same category and
e) Priority given to participate in training sessions.

**4.5.** Each HREC member is:

a) expected to become familiar with the National Statement and consult other guidelines relevant to the review of specific research applications and
b) encouraged to attend continuing education or professional development activities in research ethics once in each period of appointment.

**4.6.** HREC members and staff wishing to attend education and training should complete an Application for Conference and Study Leave or otherwise comply with local procedures.

**4.7.** The local HREC Administrator will oversee all applications, i.e., approval by authorised persons, travel arrangements through the Travel Hub and payment through Institution's Finance Department.

**4.8.** HREC members and staff are required to prepare a written report on the event and present this to the next HREC meeting. The report will be circulated to absent members and a copy held on file.

**4.9.** It is the responsibility of the HREC Administrator to maintain a register of all training provided to HREC members.

**Essential reading for HREC members**

**4.10.** For essential reading for HREC members, please refer to the Introduction section of these SOPs. HREC members may also wish to familiarise themselves with relevant sections in the

following documents. However, some documents are not available outside Queensland Health so may need to be printed for external members.

| | | |
|---|---|---|
| a) | NHMRC Guidelines under Section 95 of the *Privacy Act 1988* | Link |
| b) | NHMRC Guidelines approved under Section 95A of the *Privacy Act 1988* | Link |
| c) | *Information Privacy Act 2009* (Qld) | Link |
| d) | QH Intellectual Property Policy QH-POL-009:2015 | Link |
| e) | QH Research Management Policy QH-POL-013:2022 | Link |
| f) | QH Financial Management Practice Manual Policy QH-POL-267:2015 | Link |
| g) | *Coroners Act 2003* (Qld) | Link |
| h) | NHMRC keeping research on track: a guide for Aboriginal and Torres Strait Islander peoples about health research ethics | Link |
| i) | Australian Institute of Aboriginal and Torres Strait Islander Studies (AIATSIS) Code of Ethics for Aboriginal and Torres Strait Islander Research | Link |
| j) | NHMRC ethical guidelines for research with Aboriginal and Torres Strait Islander Peoples | Link |

# 5. HREC 005: Meeting schedules

**5.1.** A HREC should hold regular scheduled meetings of the full Committee each year for the purposes of ethics review of applications as per the National Statement (section 5) and to discuss matters relating to the establishment or operating procedures of the HREC or for training purposes.

**5.2.** The HREC must ensure that an ethics decision on an application is given within the target time limit of 60 clock days from the meeting closing date (of a validated application).

**5.3.** The schedule of HREC meetings for the year commencing on 1 January should be agreed between the HREC Administrator, HREC Chair and HREC members and submitted to ORI by for publication on the ORI website no later than 31 October of the previous year. The schedule should set out the dates, times and venues of meetings, the closing dates for each meeting (no less than 14 business days prior to each meeting) and the number of application hard copies required for submission (if applicable). All members of the HREC should be issued with details of the schedule.

**5.4.** This requirement also applies to meetings of any sub-committees.

# 6. HREC 006: Agenda

**6.1.** The HREC Administrator prepares the agenda for the meeting, which should include at least the following:

a) the date, time and venue of the meeting

b) minutes of the previous HREC meeting
c) business arising from the previous meeting(s) that the HREC specifically indicated required reconsideration
d) new applications to be considered at the meeting
e) amendments to previously reviewed documents that require full HREC review
f) any mandated reports such as annual progress reports, safety reports or final study reports and other items for noting by the HREC
g) notice of upcoming educational activities that may be of interest to HREC members
h) any general business and
i) notification of the date, time and venue of the next scheduled meeting.

**6.2.** The agenda may also include discussion of the following where appropriate:
a) general research ethics issues e.g., new guidelines or recent publications
b) matters relating to the establishment or membership of the HREC or
c) matters relating to HREC procedures.

**6.3.** All documentation sent to HREC members should be individually numbered by an agenda item.

**6.4.** The HREC Administrator should arrange the distribution of the agenda, applications and other relevant documents for review at the HREC meeting between 10 and 14 days prior to the meeting.

**6.5.** Where it is the local procedure to appoint a lead reviewer(s), the agenda should indicate the lead reviewer(s) for each application.

**6.6.** It is important that HREC meetings include sufficient applications to maintain the expertise of the HREC and justify the resources involved, but not so many as to compromise the rigour of the ethics review.

**6.7.** Minutes from a sub-committee and/or reports from external expert reviewers should be made available to HREC members for consideration at the HREC meeting or circulated sooner if available.

**6.8.** Where the HREC has previously delegated authority to the HREC Chair to give an ethics decision following receipt of further information or clarification from an applicant, the HREC should be notified, via the agenda, of the final decision taken on its behalf. A brief summary should be given of the applicant's response and the reasons for the decision taken.

**6.9.** After the meeting, the following information should be recorded in ERM once the draft minutes from that meeting have been endorsed by the HREC Chair:
a) the ethics decision given on the application
b) the members who were involved in confirming the ethics decision of the HREC and
c) whether any questions of ethical consideration arose during the review of the study.

**6.10.** The agenda and all documentation are confidential.

# 7.HREC 007: Lead reviewers

**7.1.** The HREC may appoint one or more members as lead reviewer(s) for each application.

**7.2.** Allocation of applications to lead reviewer(s) may be made by the HREC Administrator in consultation with the HREC Chair.

**7.3.** The specific role undertaken by the lead reviewer(s) both at the meeting and following the meeting is a matter for the discretion of the HREC. Local procedures should be discussed and agreed by the HREC members.

# 8. HREC 008: Meetings

**8.1.** HREC meetings must be conducted in accordance with the National Statement.

**8.2.** All validated applications requiring HREC review should be considered at a scheduled meeting of a Certified HREC or Registered HREC.

**8.3.** Under no circumstances should late new applications (i.e. those submitted after the HREC meeting closing date) be tabled at the meeting, except as described under Exceptional Circumstances, or in other exceptional circumstances, with the agreement of the HREC Chair (or their delegate).

**8.4.** All HREC members should receive a copy of the HREA for each new study, together with all supporting documentation with the following exception:

- The Investigator Brochure for an investigational product/device should be sent only to HREC members with relevant expertise (in particular, physician/pharmacist/ interventionist/surgeon), lead reviewer(s), or to all HREC members if so requested.

**8.5.** If local practices require, attach a comments sheet to each new application, on which the HREC member may record his/her comments, or alternatively use the ERM Committee function.

**8.6.** A HREC member who is unavailable to attend a meeting may submit comments in writing on any agenda item.

**8.7.** The minutes should record the submission of written comments in the attendance record, along with a notation that the HREC member was absent from the meeting.

**8.8.** A HREC member who submits written comments but does not attend the meeting counts towards the quorum of that meeting.

# 9. HREC 009: Attendance of the Co-ordinating or Principal Investigator

**9.1.** At the request of a HREC member, after discussion with the HREC Chair and acceptance by the majority of the HREC membership, the PI (or CPI for multi-centre studies) may be invited to attend a meeting (in person or remotely) at which his/her application is to be reviewed, or at subsequent meetings. The purpose of this attendance is for the PI/CPI to respond directly to requests from the HREC for further information, clarification or reassurance and NOT to make a formal presentation.

**9.2.** Where the PI/CPI unable to attend, it is acceptable for another key investigator or collaborator to attend in their place. It is not ethically acceptable for a representative of the Sponsor to attend in place of the PI/CPI. Other members of the research team or representatives of the Sponsor may also express an interest in attending alongside the PI/CPI and may do so at the discretion of the HREC Chair in consultation with the HREC membership.

**Student research**

**9.3.** All students undertaking research in Queensland public health institutions require a supervisor.

**9.4.** In the case of applications submitted by students, the HREC may consider inviting the academic or clinical supervisor to the meeting.

# 10. HREC 010: External expert reviewers

**10.1.** A HREC may seek the written advice of an expert reviewer on any aspects of an application that are relevant to the formation of an ethics decision, and which lie beyond the expertise of the HREC members or on which the HREC is unable to agree. This may necessitate going outside the membership of the HREC. These external expert reviewers may be specialists in ethics, specific diseases or methodologies, or they may be representatives of communities, patients or special interest groups.

**10.2.** For multi-centre research, the opinion of the external expert reviewer may not be used to allow the HREC to review research outside of its NHMRC certification categories.

**10.3.** For commercially sponsored studies, the cost of the external expert review may be borne, if agreed, by the Sponsor as per local policies and procedures.

**10.4.** Advice from external expert reviewers may be sought at any time by the HREC.

**10.5.** External expert reviewers are not voting members of the HREC and should not be involved in the business of the HREC other than that related to the application on which their advice is sought.

**10.6.** The HREC Administrator or HREC Chair should ensure that the external expert reviewer has declared any conflict of interest and agreed to the department and/or local HHS Conflicts of Interest Guideline and Terms of Confidentiality. For more information: QH Intranet Conflicts of Interest Guideline.

**10.7.** If possible, a copy of the advice received from the external expert reviewer should be made available to HREC members prior to the meeting or tabled at the meeting.

**10.8.** The external expert reviewer may be invited to attend the meeting in person for discussion of the application concerned.

**10.9.** Where a HREC decides that it cannot give a decision until it has obtained further advice from an external expert reviewer, the following procedure should be adopted:

- a letter or email should be sent to the applicant following the meeting, explaining that no decision has been taken on the application, pending consultation with an external expert reviewer, and

- the letter or email may notify the applicant of the issues of concern to the HREC but should not at this point request further information or clarification from the applicant.

**10.10.** In some cases, the HREC may decide at the meeting with whom it wishes to consult, and if so, this should be recorded in the minutes. If not, either the HREC Chair or the HREC Administrator should be appointed to identify a suitable external expert reviewer urgently following the meeting.

**10.11.** The HREC Chair or HREC Administrator should initially contact the prospective expert external reviewer by phone or email to establish whether they are willing and able to provide expert advice within the required timeframe.

**10.12.** It should be established that the prospective external expert reviewer has no connection with the research that might give rise to a conflict of interest. A confidentiality agreement should be signed by the external expert reviewer prior to the HREC Administrator forwarding the application for review.

**10.13.** Once a suitable external expert reviewer has been identified, the HREC Administrator should formally write to the external expert reviewer. This letter or email should be as specific as possible about the issues of concern to the HREC and the nature of advice required.

**10.14.** A copy of the application should be provided, together with any supporting documentation required by the external expert reviewer. Where possible, the letter or

email should be sent within five business days of the meeting. The external expert reviewer should be asked to respond in writing within a further 14 business days.

**10.15.** Once the external expert reviewer's advice has been received, it should be considered at a meeting of the sub-committee or at a further meeting of the HREC if time allows. If the expert review is required to enable the HREC Chair to make a decision prior to the next HREC meeting, the expert review should be circulated to the HREC membership electronically. The HREC should either reach a decision on the application at this point or request further information from the applicant. Whichever decision is given, the procedures set out for determining a decision should be followed.

**10.16.** The HREC will not disclose the nature of the external expert reviewer's advice to the applicant unless it is relevant to be presented as feedback to the applicant from the HREC. The decision the HREC reaches on the application is its own. The HREC will not disclose the identity of the external expert reviewer/s except with their express permission.

# 11. HREC 011: Declaration of conflict of interest

**11.1.** HREC members should declare any conflict of interests they may have in relation to an application for ethics review or any other matter for consideration at the meeting.

**11.2.** Such a declaration may be made:

- verbally at the meeting
- verbally prior to the matter being considered or
- in writing to the HREC Chair prior to the meeting.

**11.3.** Where the HREC member concerned is the PI or another key investigator/collaborator named on the application form, the HREC should not proceed with the review until the member has excused themselves from the meeting room. If necessary, the member can be invited back into the room to answer questions raised by the HREC but should leave the room again when the discussion and deliberations resume.

**11.4.** In the case of any other declared conflict of interest, the HREC should collectively consider whether or not it is appropriate for the HREC member concerned to take any part in the review of the application. Account should be taken of the closeness of the member's interest in the application and the potential for a conflict of interest. In some cases, the declaration of the conflict of interest may in itself be sufficient to ensure that the decision of the HREC is not unduly influenced.

**11.5.** The minutes should record any declaration of conflict of interest and the decision of the HREC on the procedure to be followed.

**11.6.** Any conflict of interest pertaining to HREC members, researchers, institutions, and all other stakeholders should be considered in accordance with QH Research Management Policy (for the department staff) and Research Ethics and Governance Health Service Directive (for HHSs) as well as Chapter 5.6 of the National Statement.

# 12. HREC 012: Confidentiality

**12.1.** HREC members need to be able to discuss freely the applications submitted to them. For this reason, HREC meetings should be held in private, and members should be encouraged to raise any matters of concern.

**12.2.** The terms and conditions of appointment for HREC members include requirements to keep the business of the HREC confidential.

**12.3.** All members of the HREC should be indemnified and sign confidentiality agreements.

**12.4.** It is permissible for members of other HRECs, students studying ethics components and other persons to approach the HREC Chair to request permission to attend a HREC meeting as an observer. Before this occurs, permission must be granted by the HREC Chair and a confidentiality agreement must be signed by the observer.

**12.5.** Once an application has been submitted for review, all further correspondence with the applicant relating to the application should be treated confidentially by the HREC.

**12.6.** No copies of letters should be sent directly by the HREC to the Sponsor(s) of the research, unless agreed by the CPI/PI. Generally, all correspondence is between the CPI/PI and the HREC. However, the applicants can provide access to all documents by any of the project team (including Sponsors within ERM at their discretion).

# 13. HREC 013: Decision making

**13.1.** The HREC Chair is responsible for the conduct of business at HREC meetings and for ensuring that the HREC reaches clearly agreed decisions on all matters. Where the HREC Chair is unavailable, HREC meetings should be chaired by the Deputy Chair or, if the Deputy Chair is also unavailable, by another HREC member, as determined by the HREC Chair (provided that the quorum can still be met).

**13.2.** All HREC members present at a HREC meeting, both expert and lay, should be allowed reasonable opportunity to express relevant views on matters on the agenda. In accordance with section 5.2.22(c) of the National Statement, if HREC members are unavailable for a meeting they should provide opinions on the ethical acceptability of research proposals before meetings, subject to institutional policies on absences.

**13.3.** The written opinions of absent members should be tabled at the meeting and considered as part of the deliberation of a research project and noted in the minutes.

**13.4.** Decisions by an HREC about whether a research proposal meets the requirements of the National Statement must also be informed by an exchange of opinions from the relevant quorum. This exchange should, ideally, take place at a meeting with all those members present The HREC should endeavour to reach decisions by general agreement.

**13.5.** Generally, the minutes will record discussion of significant issues and the decision given.

**13.6.** Where any HREC member wishes to record their formal dissent from the HREC's decision, this should be recorded in the minutes.

# 14. HREC 014: Decisions available to the HREC

**14.1.** A HREC should reach one of the following decisions on any application reviewed at a meeting:

a) Final decision. The HREC may reach a final decision on the application at the meeting. This decision may be Approved or Not Approved.

b) Further information/modification requested. The HREC may look favourably upon a project but will seek further information/clarification before making a final decision. The application should be given a decision of Further information/modification requested. The application should not be given a decision of Not Approved at this time.

c) After reviewing the requested clarifications, the outcome will be:

I. Assign to Reviewer. The HREC may decide that no decision can be given until an external expert reviewer has been consulted.

II. Invalid application. The HREC may decide that the application is so incomplete that they are unable to review the application and the applicant must submit the application again as a new submission.

III. Approved or Not Approved, or

IV. Exempt QA/Not research *E/Exempt research *E. The HREC Chair may decide that the application does not require review by the HREC. Examples of HREC review exemptions can be some lower risk with non-identifiable dataset research and QA projects.

**14.2.** The HREC Chair must ensure that one of the above decisions is recorded for every application considered at a HREC meeting.

**14.3.** The HREC Administrator should ensure that the minutes clearly record the decisions taken by the HREC, any further information requested from applicants, and the agreed procedures for considering that information and confirming a final decision.

**14.4.** In making an ethics decision, the HREC Chair or delegate may decide to allow other persons access to HREC application files such as an external expert reviewer. This decision may be taken at a HREC meeting or between meetings. The rationale for allowing access to HREC files is to be recorded in the minutes at the next HREC meeting.

## HREC decision timeframe

**14.5.** A HREC is required to undertake the scientific and ethical review of an application and give a decision within 60 clock days. For research not requiring review at a full HREC meeting, the clock starts on the receipt of a valid application. For research requiring review at a full HREC meeting the clock starts on the relevant HREC meeting closing date.

**14.6.** Where the HREC considers that further information or clarification is required in order to give a decision, the HREC may request, in writing, further information from the applicant. The clock will be suspended pending receipt of this information and will re-start automatically when a response from the applicant is logged into ERM.

**14.7.** If the HREC is unable to give a final decision on an application within the 60 clock days period, the following guidance is given:

a) the HREC may, with agreement from the applicant, continue the review of the project, until such time as a decision is reached, or

b) the HREC gives the project a decision of Not Approved, and the applicant is given the option of:

I. Re-submitting a new application, with a new HREC number to the same HREC.

II. Submitting their application to a new HREC, but in doing so, must disclose the Not Approved decision of the first HREC, with an explanation of the concerns of the first HREC or

III. Withdrawing the application all together.

**14.8.** All HREC reviews exceeding 60 clock-days are monitored by the department to assess if any remedial actions are required to be implemented.

## Notification of the decision to the PI or CPI

**14.9.** The HREC Administrator should ensure that, following confirmation of the minutes by the HREC Chair, notification of the decision is sent in writing to the PI/CPI within four business days of the meeting. Initial notification to the researcher of the HREC's decision may be via ERM or email from the HREC Administrator or HREC Chair.

**14.10.** In all cases, the decision reached by the HREC should be communicated in the notification letter. The letter should also include:

a) those areas of concern for the HREC, for which further information is being requested and

b) the HREC's decision on any issues for which the applicant has specifically requested an opinion.

**14.11.** The letter should not attribute particular comments or questions to individual members of the HREC.

**Request for further information**

**14.12.** Where the HREC decides that further information or clarification is required, the applicant is notified in writing about the requested clarifications.

**14.13.** Requests for further information or clarification may include recommendations or requested changes to the application or any of the supporting documentation, for example the Participant Information and Consent Form (PICF).

**14.14.** Requests for further information or clarification may occur a number of times until such time the HREC agrees a final valid response to their request has been received.

**14.15.** When seeking further information or clarification from the applicant, the HREC Chair should ensure that:

a) The further information or clarification required has been specifically identified at the meeting and recorded in the minutes.
b) The applicant is advised to submit a revised HREA; provide a cover letter clearly addressing the questions asked by the HREC; and upload all revised documentation in both tracked changes and clean format e.g. study protocol, participant information sheets and consent forms etc. Changes to previous versions of the HREA can be seen in ERM. All new documentation is to be uploaded against the original application in ERM. New version details are required where appropriate.
c) Delegation of responsibility for considering the further information and confirming the HREC's final decision is clearly agreed and included in the letter of notification, i.e. the information will need to be re-submitted to the full HREC, a number of HREC members or the HREC Chair only and
d) The questions asked by the HREC are based on references to the National Statement.

**Delegation of responsibility by the HREC**

**14.16.** Where the HREC has made the decision to request clarification of information, or the provision of further information and/or modification/s to the study, the Reviewing HREC will establish a procedure for considering correspondence received from the PI/CPI which may include one of the following:

a) Delegation of authority to review the interim correspondence and approve the study between meetings at the discretion of an Executive Committee of the HREC, comprising of one or more HREC members.
b) Delegation of authority to review the correspondence and approve the study between meetings at the discretion of the HREC Chair alone,
c) Consideration of correspondence at a future meeting of the HREC, or
d) Delegation of authority to the HREC Administrator (administrative or minor amendments).

**14.17.** To provide suitable governance of this delegated authority to review the correspondence and approve the study between meetings, the HREC must ratify the final decision taken on its behalf at the next available meeting. This should include the applicant's response and the reason for the decision taken.

**14.18.** In deciding the procedures to be followed, the HREC should consider the significance of the further information and the degree of ethical judgement necessary to evaluate it. Where the information is straightforward, it is acceptable for the matter to be delegated to the HREC Chair alone. Where questions of ethical judgement are likely to arise, or specific clinical or scientific expertise is required, consideration should be given to involving other members, such as the lead reviewer(s) or a relevant expert reviewer. Where these questions are likely to be significant, a sub-committee meeting should be arranged so that they can be fully discussed.

**14.19.** It may be decided that the response should be considered at a further meeting of the HREC. When taking this course of action, the HREC should take into account the 60 clock-day time limit. If the applicant fails to submit their response by the closing date for the next scheduled meeting, it will be submitted to the following scheduled meeting unless otherwise arranged with the HREC Chair.

**Suspension of the clock**

**14.20.** The clock should be suspended from the date on which the request for further information is sent to the applicant, post HREC review. It re-starts when a valid response is registered on ERM, not the date on which the information is considered by the HREC.

**14.21.** Where possible, the HREC should encourage informal communication with applicants and should consider face-to-face (or virtual) meetings to resolve issues about research proposals that have not been resolved by written or telephone communication.

**14.22.** A period of three months or two meetings should be allowed to respond to the request for further information. The researcher should be informed that if no response is received within this time, the HREC will consider the application to be withdrawn and will require a new application if the project is to proceed. The applicant should also have the opportunity to request an extension to this timeframe in writing to the HREC Chair, outlining their reasons. An extension request may not always be agreed.

**Final decision following consideration of the information**

**14.23.** On receipt of a valid response from the applicant, the HREC should confirm its final decision on the application, which may be Approved or Not Approved. The procedures set out below should be followed.

**Letters giving the HREC's final decision**

**14.24.** The final decision of the HREC will form part of the recommendation to the Department/HHS CE or delegate for Authorisation to conduct the research at a site. The

letter notifying the final decision of the HREC review should be sent to the applicant no later than 60 clock days from the validation date.

**When the application is approved**

**14.25.** Where the final decision is Approved, the HREC Approval letter should list the following items:

a) A list of all documents reviewed and approved at the meeting, outlining version numbers and document dates.
b) The list of sites for which the HREC decision is valid considering SOP 21.11 "state-wide" research (multi-centre research only).
c) The period of HREC Approval or as per institutional HREC process'.
d) The date on which the application was approved (noting that this will be different from the date on which the letter is signed).
e) The HREC approval anniversary date.
f) Date(s) on which the CPI submits to the Reviewing HREC, a progress report which includes reporting from all approved sites
g) Any specific reporting requirements for the study.
h) Standard conditions for research approved by the HREC.
i) Specific HREC Approval requirements e.g. the waiving of the requirement for consent.
j) The application of any privacy guidelines or legislation. For more information: Guidelines approved under Section 95A of the *Privacy Act 1988*.
k) Notes regarding specific governance matters such as consideration of PHA and HHB Act permissions or that the applicant should contact the RGO with regards to the possibility of a waiver of the requirement to complete an SSA Form, or whether modified research governance process may be appropriate.
l) Indicating that the research cannot commence until site authorisation has been endorsed by the participating site RGO and
m) The HREC composition of the membership of the HREC in attendance at the meeting at which the application was reviewed. This includes the membership category, gender and institutional affiliation. The HREC composition should be provided with the HREC approval letter.

**14.26.** Where the Reviewing HREC is at a different site from the only participating site in a single site study, the name of the participating site should also be included in the HREC Approval letter.

**When the application is not approved**

**14.27.** Where the final decision is Not Approved, the applicant should be given a full explanation of the HREC's reasons with reference to the National Statement. The applicant should also be informed of the options available for further review or appeal, as below.

**Further review following a not approved decision**

**14.28.** The applicant has the following options available:

a) New application may be submitted to the same HREC (and no other HREC), taking into account the HREC's concerns. This should be processed and reviewed in the same way as any other new application or

b) The applicant may lodge a complaint with the HREC Chair, and the process should be followed as outlined in SOP 45 Handling research complaints and potential breaches of the Code.

# 15. HREC 015: Minutes

**15.1.** The minutes of the HREC meeting should be prepared by the HREC Administrator in consultation with the HREC Chair and other members as necessary. The minutes should be approved by the HREC Chair within three business days following the meeting.

**15.2.** In relation to applications for ethics review or notices of substantial amendment, the minutes should contain an accurate record of the following, whether in the main text of the minutes or in attachments:

a) Attendance and apologies of the HREC members and external expert reviewers present for the review.
b) Any conflicts of interest declared, and the decision of the HREC regarding allowable level of participation of the HREC member concerned.
c) The submission of written comments by HREC members.
d) The substance of any advice given by an external expert reviewer.
e) The decision of the HREC regarding the application.
f) A summary of the main ethics issues considered and references to the National Statement where appropriate.
g) In the case of further information being requested, any special approval conditions or additional advice to be given to the applicant, as well as the arrangements for considering the information and confirming the final decision of the HREC.
h) Where the opinion of an external expert reviewer is sought, the issues on which further advice is required.
i) In the case of a not approved decision, the reasons for the decision with reference to the National Statement need to be specified.
j) Any formal dissent from the decision of the HREC by a named member, with reasons for their dissent.

**15.3.** The minutes should be submitted to the next meeting of the HREC for ratification as a true record. Any necessary revisions should be incorporated in the final version of the minutes, which should be signed and dated by the HREC Chair.

**15.4.** Minutes are confidential to the HREC and should not be disclosed to applicants, Sponsors or host organisations.

# 16. HREC 016: Duration of HREC approval

**16.1.** The duration of the HREC Approval 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 HREC Approval letter.

**16.2.** The duration of a HREC Approval is individually assessed for each project, taking into consideration the level of risk associated with the study, and based on the researcher's estimated study duration. HREC Approvals may be granted as rolling approvals (contingent on submission of annual reports) or for a period of time e.g., subject to provision of annual reports, except where action is taken by the Reviewing HREC to suspend or terminate a project.

**16.3.** Principle 7 of the NMA Standard Principles for Operation require that scientific and ethical approval will be for up to a five-year period or rolling approval for the life of the project.

**16.4.** The duration of the HREC Approval is recorded on ERM under a custom data field.

**16.5.** If a researcher wishes to extend the duration of their HREC Approval, they must request an amendment via ERM to the HREC, outlining why and for how long the extension is required.

**16.6.** The decision of the HREC to grant the extension will depend on the type of study, compliance with HREC reporting requirements, and circumstances which have brought about the need for the extension as applicable to and upholding the four principles of the National Statement.

**16.7.** Once HREC approval has been granted, the research should commence within 12 months of the date of ethics approval.

**16.8.** The Study Start date refers to either the anticipated first point of recruitment (i.e., the date when the advertising or screening for participants begins) or data collection, at a site.

**16.9.** If the study has not commenced within 12 months, the PI should provide the HREC with a written explanation for the delay. It is up to the HREC to permit a further 12-month period in which the research should commence.

**16.10.** If the project does not commence within 24 months of the original approval date, the matter should be discussed at the next HREC meeting. At the discretion of the HREC, study approval may be withdrawn, and the PI required to submit a new application once the problems relating to the delay of the study have been fully addressed.

# 17. HREC 017: HREC reporting requirements

**17.1.** The ratified minutes of each HREC meeting are forwarded to the Chief Executive or delegate.

**17.2.** The HREC provides an annual report to the Chief Executive or delegate, which includes:

a) Membership/membership changes.
b) Number of meetings.
c) Number of research projects reviewed, approved and rejected.
d) Monitoring procedures for ethical aspects of research in progress and issues identified by the HREC in undertaking its monitoring role.
e) Description of any appeals and complaints received and their outcome.
f) Description of any research where HREC approval has been suspended or withdrawn and the reasons for this action.
g) General issues including advice on strategies to promote awareness of the ethical conduct of human research in the institution and
h) Resources to assist the HREC in fulfilling its role.

**17.3.** The HREC completes and submits reports on behalf of the department/HHS to the:

a) Australian Health Ethics Committee (AHEC) in accordance with the requirements of the NHMRC.
b) [For certified institutions only] Certified Institution Annual Report to the National Health and Medical Research Council (NHMRC), and any other reports as required.

# 18. HREC 018: Clinical Trial Notification and Clinical Trial Approval schemes

**18.1.** HRECs play an important role in the regulation of the supply of unapproved therapeutic goods under the *Therapeutic Goods Act 1989* in connection with the operation of clinical trials via the Clinical Trial Notification (CTN) Scheme, the Clinical Trial Approval (CTA) Scheme, the Special Access Scheme and approval of Authorised Prescriber Scheme.

**18.2.** Unapproved therapeutic goods have undergone little or no evaluation of quality, safety or efficacy by the TGA. These products are considered to be experimental and potentially carry some risks that have not been defined in the Australian context. HRECs should be guided by the principles outlined in the National Statement in assessing the risks, benefits and precautions in research involving humans.

**18.3.** In particular, the following should be noted:

a) The difference between the CTN and CTA schemes is the level of involvement of the TGA in reviewing data about the therapeutic good involved in the trial before the trial begins.

b) CTN: The TGA does not review any data before the trials begins. The responsibility for the review lies with the HREC and PI. The HREC and institution should establish what information will be provided in support of an application and how that application will be handled by the HREC. Only one protocol can be conducted per CTN.

c) CTA: The TGA reviews summary data about the therapeutic good (medicine or medical device). The CTA scheme approves usage guidelines for one medicine or one medical device and any number of protocols, all relating to the one medicine or the one medical device, can be conducted within the scope of those usage guidelines.

d) HRECs are responsible for reviewing clinical trial protocols for both CTN and CTA. Responsibility for the conduct of the trial rests with the PI and authorisation to conduct the trial rests with the institution or body where the trial is to be undertaken and

e) In approving a trial protocol, under both the CTN and CTA schemes, the HREC is assuming responsibility for monitoring the conduct of the trial. The CTN is an electronic form and the CTA is currently paper based. The regulatory submission of the CTN and CTA is the responsibility of the Sponsor.

# 19. HREC 019: Authorised prescriber applications

**19.1.** In accordance with the Therapeutic Goods Act 1989, Therapeutic Goods Regulations 1990 and Therapeutic Goods (Medical Devices) Regulations 2002, the Therapeutic Goods Administration (TGA) is able to grant to a medical practitioner authority to prescribe a specified unapproved therapeutic good or class of unapproved therapeutic goods to specified recipients or classes of recipients (identified by their medical condition). An Authorised Prescriber can then prescribe that product for that condition (also known as the 'indication') and no approval from the TGA is required for each individual patient. Full details of Authorised Prescriber Scheme is available from the TGA at Authorised Prescribers | Therapeutic Goods Administration (TGA)

**19.2.** There are two pathways to apply to become an Authorised Prescriber, depending on the product to be prescribed and whether it has an 'established history of use'. Medicines deemed to have an established history of use are specified in subregulation 12B(1B) and 12B(1C) of the Therapeutic Goods Regulations.

**a) Pathway 1:** The 'Established history of use pathway' requires one application to be submitted to the TGA for medicines deemed to have an established history of use. HREC approval or specialist college endorsement is not required before applying to the TGA. Prescribers will still need to check institutional requirements.

**b) Pathway 2:** The 'Standard pathway' requires a 2-step application process for products that are not **included** in sub-regulation 12B(1B) of the Therapeutic Goods Regulations 1990. Before applying to the TGA, the practitioner must obtain endorsement from the HREC at the institution at which they practise (except where the practitioner can demonstrate that he/she does not have access to an appropriate ethics committee, in which case endorsement from a specialist college is acceptable). The HREC is responsible for providing a letter of endorsement to be submitted by the medical practitioner to the TGA as part of the practitioner's application. Guidance for HRECs can be found here: https://www.tga.gov.au/form/authorised-prescribers#faqs

**19.3.** When reviewing applications to become an Authorised Prescriber, HRECs needs to assess not only the safety of the product in relation to its proposed use, but also the suitability of the medical practitioner. The HREC should consider:

a) The indication for which the product will be prescribed.
b) Efficacy and safety of the product in relation to its proposed use.
c) For medicines, the route of administration and dosage form.
d) Clinical justification for use of the product.
e) Suitability of the medical practitioner and
f) Patient information about the product and the informed consent form.

**19.4.** If endorsed, the HREC provides a letter to the applicant in the format suggested by the TGA. The HREC may impose conditions on the endorsement, if required, such as:

a) Regular reports to the HREC comprising information such as the number of patients prescribed the unapproved product
b) Reporting of Adverse Events.

**19.5.** The HREC should review its endorsement of the Authorised Prescriber if it is aware of:

a) Inappropriate use of the product by the Authorised Prescriber.
b) Safety concerns about the product.
c) Failure of the Authorised Prescriber to comply with conditions imposed by the HREC or
d) Failure of the Authorised Prescriber to comply with legislation.

**19.6.** Where the HREC is not satisfied that the welfare and/or rights of patients are not or will not be protected, it will:

a) Advise the medical practitioner and the relevant CE of its concerns.
b) Withdraw its approval of the Authorised Prescriber if it is satisfied that the welfare and/or rights of patients are not or will not be protected and
c) Report to the TGA (if the relevant CE and HREC Chair determine escalation i).

**19.7.** To review access to unapproved therapeutic goods via Authorised Prescribers, the HREC and the Department/HHS/institution/facility will determine the best process for considering applications. This process may consist of:

a) Determination by the HREC Executive Committee and/or
b) Consultation with the hospital drug and therapeutics committee or delegate and/or
c) Consultation with the scientific subcommittee.

**19.8.** Decisions by the HREC Executive Committee are tabled for ratification at the next HREC meeting.

**Institutional approval**

**19.9.** Final responsibility for the use of an unapproved product within an HHS/institution/facility always rests with that HHS/institution/facility. Medical practitioners working in an HHS should discuss the use of the unapproved therapeutic product and identify their local approval process(es) before applying for authorisation. The HREC may ask for evidence of institutional support/process consideration when reviewing Authorised Prescriber applications.

# 20. HREC 020: General Guidance and workflow

**20.1.** Applicants should be encouraged to submit applications for HREC review on any day, not just the closing date to decrease workflow pressures of submission deadlines.

**20.2.** All proposed research must comply with the current version of:

- the National Statement and
- the NHMRC, Australian Research Council and Universities Australia Australian Code for the Responsible Conduct of Research (2018).

**20.3.** All research applications reviewed by a QH HREC are to be submitted using the nationally recognised Human Research Ethics Application (HREA) form.

**20.4.** All research applications will be administered through the QH endorsed IT platform, Ethics Review Manager (ERM): https://au.forms.ethicalreviewmanager.com/ (or its replacement).

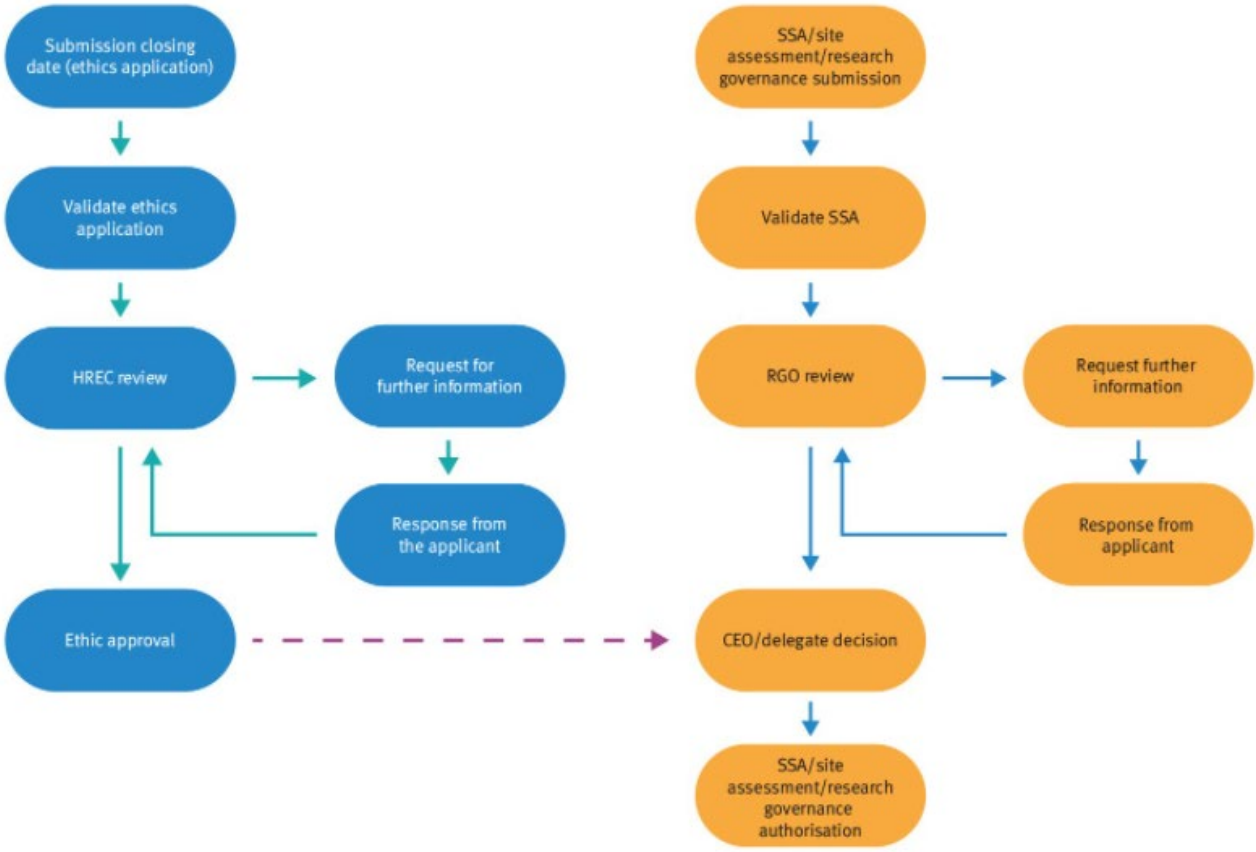
**20.5.** Please refer to the ERM manual for processes with the ERM system (help tab) – https://qld.review.ethicalreviewmanager.com/

**20.6.** All new applications for ethics review are to be submitted using the ERM version of the HREA accessed via https://au.forms.ethicalreviewmanager.com/

**20.7.** If a researcher competes the NHMRC HREA version, it is their responsibility to import this into ERM.

**20.8.** Please refer to appendix 2 for guidance on the promotion of external research with Queensland Health newsletter and communication.

**Standardised Research Ethics and Governance Workflow**




# 21. HREC 021: Multi-centre Studies, NMA and MOUs

**21.1.** For multi-centre research studies, a HREC that has been included in the National Mutual Acceptance (NMA) scheme is the single HREC body to conduct the ethics and scientific review of a multi-centre research study, conducted in publicly funded health services.

**21.2.** All multi-centre studies will have only one CPI.

**21.3.** Submission of a multi-centre research project, for review by a Certified HREC listed in Queensland Health Memoranda of Understanding (MOU) for NMA or other published agreements, will be made via ERM.

**21.4.** The scope of this MOU for NMA includes reviews (that is, ethical and scientific reviews, in accordance with the National Statement, by Certified HRECs of Multi-Centre Human Research Studies) and expressly excludes the following:

a) research studies that are not 'multi-centre' in that they are not proposed to be conducted at participating organisations of more than one party and, in relation

to Queensland Health, are not proposed to be conducted at sites of more than one Hospital and Health Service (such studies will be ethically and scientifically reviewed in accordance with the individual requirements of the Party conducting it) and

b) research studies involving access or use of coronial material (such studies must be referred to the Queensland Health Forensic and Scientific Services Human Ethics Committee (FSS-HEC) for ethical and legal approvals).

**21.5.** There is also an MOU between QH, Mater Misericordia Ltd (Mater) and the Council of the Queensland Institute of Medical Research (QIMR Berghofer) for Mutual Acceptance of single ethical and scientific review of multi-centre human research studies.

**21.6.** A HREC may communicate with the CPI or nominated Site Coordinator or contact person. It is the researcher's responsibility to identify to the HREC Administrator who the most appropriate contact person is for the project by listing a contact person on the HREA and subsequent amendments.

**Conducting the HREC review under NMA and other MOUs**

**21.7.** Eligible multi-centre research will be reviewed only once by a Certified HREC under the NMA scheme.

**21.8.** Where there is a Site located in Victoria or Western Australia, the State Specific Module must be completed as required (preferably by a researcher from the relevant state/territory, as nominated by the CPI (in consultation with the trial sponsor where applicable) and submitted by the CPI, along with the HREA and all other supporting documentation, to the Reviewing HREC.

**21.9.** The HREC approval will apply to all participating sites, as identified in the HREA with the exception to research such as surveys where participants may originate from many different facilities but where it is not practical to nominate a PI or contact person at each facility.

**21.10.** For the purposes of HREC correspondence communicating a decision relating to approval of multi-centre research proposed to be conducted at multiple sites within QH, it is sufficient to specify in the correspondence only the HHS(s) within which the research is proposed to be conducted because the decision will apply to all participating Sites within each HHS at which the research is proposed to be conducted.

**21.11.** The term "state-wide" may be used to describe research projects in which research is proposed to be conducted at more than one HHS /the Department.

**21.12.** Clinical trials must comply with the National Standard Operating Procedures for Clinical Trials, Australian Government Department of Health: https://www.health.gov.au/resources/publications/national-standard-operating-procedures-for-clinical-trials

**21.13.** Where applicable, clinical trials must be conducted in accordance with the requirements of:

i. the Therapeutic Goods Administration Act 1989 (Cth).
ii. the adopted Therapeutic Good Administration ICH Guideline for Good Clinical Practice and
iii. ISO 14155 Clinical investigation of medical devices for human subjects - Good Clinical Practice (for medical devices).

**21.14.** Studies allocated to a HREC for review under the NMA are processed the same as any multi-centre study except that they are noted as NMA projects in ERM.

**21.15.** All participating sites for which the HREC review is valid must be listed on the HREC Approval letter.

**21.16.** For a list of NMA participating organisations, or for further information refer to: https://www.clinicaltrialsandresearch.vic.gov.au/national-mutual-acceptance (noting that all states have agreed that Victoria is the web site host for all NMA documentation).

**Research not included in NMA**

**21.17.** Some types of research and some clinical trials are excluded from NMA because of state specific requirements. For further information refer to: https://www.clinicaltrialsandresearch.vic.gov.au/national-mutual-acceptance to view the current types of research excluded from NMA.

**21.18.** For research conducted in Queensland:

a) research projects involving access or use of coronial materials must be referred to the Queensland Health Forensic and Scientific Services Human Ethics Committee (FSS-HEC) for ethical and legal approvals.

**21.19.** The excluded studies will continue to be reviewed under the current local jurisdictional arrangements. Researchers should contact their local HREC if unsure of the process or require further detail.

**21.20.** The HREC Chair may approve a project through expedited review if it has previously been reviewed by a certified HREC that is non-NMA, provided they are confident the project has been thoroughly assessed against the National Statement and meets ethical standards. A A HREA will require submission via ERM however, the review may occur outside of a committee meeting. HREC indemnity remains necessary, and local fee structures will apply.

**Memorandum of Understanding (MOU) for Mutual Acceptance**

**21.21.** Only one HREC review is required for multi-centre research studies being undertaken within QH, QIMR Berghofer and Mater.

**21.22.** The HREC review from the QIMR Berghofer and Mater HRECs is accepted throughout Queensland Health for all types of research.

**21.23.** All Multi-Centre Human Research Studies sponsored by QIMR Berghofer must be reviewed by a QIMR Berghofer Certified HREC.

**21.24.** All Multi-Centre Human Research Studies sponsored by Mater must be reviewed by a Mater Certified HREC.

**21.25.** The QIMR Berghofer and Mater HRECs are not Reviewing HRECs in the NMA MOU, therefore the review of QIMR Berghofer and Mater HRECs will not be accepted in public institutions outside of Queensland under NMA arrangements.

**21.26.** QIMR Berghofer and Mater can participate in the NMA scheme as an accepting site.

**21.27.** If a research project has been reviewed and approved by a HREC (included in a relevant MOU) that is not certified to review multi-centre research, or, if a Certified HREC has reviewed a project that falls outside of the categories included in the NMA model, an institution may make a decision to accept the HREC review of the original approving HREC. The decision to accept the original HREC approval is the decision of the relevant HHS/institution/facility's RGO, HHS CE (or their delegate) (noting the HREC must be included in a relevant MOU).

# 22. HREC 022: Inclusion of private sites in a HREC review

**22.1.** Sites to be covered by the HREC review must be listed in the application. This includes sites where information will be gathered from and where the information will be analysed. If there are private institutions listed, the following points must be considered:

a) does the private institution have its own HREC and has it reviewed this project?
b) will the private institution accept the review of a Department/HHS HREC?
c) is there an agreement in place between the HREC and the private institution to allow HREC monitoring of the project in the private institution, including access to patient data?
d) for commercially sponsored research if the institution responsible for the HREC is not a participating site, has the private institution been listed on the Form of Indemnity – HREC Review Only?
e) for investigator-initiated research, has the private institution offered indemnity to the Department/HHS and HREC (as applicable)?
f) is disclosure of information from a Commonwealth agency required as part of the project?
g) does the proposal require use or disclosure of personal information?
h) is section 95 or 95A of the Privacy Act 1988 required to be considered/applied by the HREC?

# 23. HREC 023: Teletrials

**23.1.** The conduct of the trial is detailed under the 'head agreement', (Clinical Trial Research Agreement/Clinical Trial Agreement between the Sponsor and the Principal Investigator's Institution) and a Sub-Contract between the Primary Site and the Satellite Site Institutions (see Teletrial Sub-Contract). A Supervision Plan is required, in addition to a Delegation Log required by ICH GCP for all Satellite Sites regardless of experience. Trial participants may have trial visits at both the Primary and Satellite Sites, as determined by the Protocol and Supervision Plan.

**23.2.** The NHMRC Certified HREC that undertakes the review of the ethics application for the project that includes Teletrial methodology is notified of the establishment of clusters and the addition of any new Satellite Sites joining the cluster on an ad hoc basis as such additions occur. The Reviewing HREC does not approve clusters or Satellite Sites but is requested to consider any changes to the Consent processes that may be required as a result of conducting the clinical trial under the Teletrials model.

**Clinical Trial Notification (CTN) in Teletrials:**

**23.3.** It is the Sponsor's responsibility to submit and maintain the CTN form. If pathology kits for a clinical trial contain unregistered therapeutic goods, every site that stores a supply of pathology kits must be listed on the CTN form, regardless of whether the IMP is being stored at that site.

**23.4.** Satellite Sites do not need to be named on the CTN if Investigational Product/s (and pathology kits containing unregistered therapeutic goods) are not being stored at the Satellite Site but are only being shipped to the Satellite Site on a visit-by-visit basis. If Investigational Product/s are being stored at the Satellite Site (regardless of whether pathology kits containing unregistered therapeutic goods are stored at the site), the Satellite Site must be named on the CTN.

**23.5.** When Satellite Sites join a cluster after the clinical trial has commenced, the same applies. If Investigational Products are being shipped to or stored at the new Satellite Sites, the Sponsor must update the CTN form. However, where there is uncertainty, the TGA advises that any site that is undertaking clinical trial related activities should be named on the CTN form.

a) If Investigational Product/s or pathology kits containing unregistered therapeutic goods are being stored at the Satellite Site:
   I. the Satellite Site is identified as a Site on the CTN
   II. the PI from the Primary Site should be identified as the Satellite Site Principal Investigator
   III. the Approving Authority is the Satellite Site's legal entity name.

b) If the Investigational Product/s and pathology kits containing unregistered therapeutic goods are being stored at the Primary Site and are only being shipped to the Satellite Site on a visit-by-visit basis:
   I. the PI should be identified as the Primary Site PI
   II. the Approving Authority is the Primary Site legal entity name
   III. Satellite Sites are not named on the CTN.

**23.6.** It is the responsibility of the Primary Site to notify the CPI of the Sponsor's agreement to conduct the trial under the Teletrials Model (if this has not already been established and approved by the HREC).

a) evidence of the Sponsor's agreement to conduct the trials under the Teletrials Model
b) clarification as to whether the Optional Teletrials Specific Wording was included in the Master PICF/s; if not, the CPI should be requested to submit an amended Master PICF/s to include the Optional Teletrials Specific Wording
c) the specific manner in which informed consent will be collected at the Satellite Site/s
d) updated CTN and Form of HREC Indemnity, depending on Sponsor agreed processes.

NB. Operationally within a HHS where access to clinical trials can be provided to patients across more than one site and where HREC approval has been granted for the entire HHS, the teletrial cluster approval is a Research Governance Officer process..

**Guidance documents**

**23.7.** For Teletrial specific reading and documentation for HREC coordinators:

| | | |
|---|---|---|
| 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) | Notification to reviewing HREC of satellite site joining a teletrial | Link |

# 24. HREC 024: Processing steps for applications

**24.1.** The decision on whether an application is complete or incomplete can be made by the HREC Administrator, although if in doubt the HREC Chair should be consulted.

**24.2.** For incomplete or invalid applications, the PI/CPI and/or study contact person will be notified by the HREC Administrator that:

a) The application will not be accepted for the next HREC meeting and that the application will require further attention by the CPI/PI/contact person prior to HREC review (the applicant should be given guidance on remedial action), or

b) The PI/CPI/contact person must supply further information in relation to the application by a specific date or time advised by the HREC Administrator for the application to be reviewed at the upcoming HREC meeting.

**24.3.** The research application will be acknowledged by the HREC Administrator by changing the status in ERM (or its replacement), within two business days of submission.

**24.4.** Upon acknowledgement of an application, the HREC Administrator must check the following:

a) All required signatures are in the application and

b) All data from the HREA and the supporting documents are uploaded into ERM, and that the application is complete.

**24.5.** If all supporting documentation has not been uploaded, then the HREC Administrator will request the applicant upload all required supporting documentation to the ERM application by returning the submission to the applicant for further editing. An administrative review and feedback to the applicant of new submissions must be completed within seven business days of acknowledgement of the application.

**24.6.** The HREC Administrator must check that all relevant submitted documentation has correct version details and descriptors when registered on ERM. This will ensure that the approval documentation is correct and complete. Where inconsistencies are found, the HREC Administrator should contact the applicant to notify them that the application will not be deemed valid until corrected.

**24.7.** The provision of hard copies and/or cover letters may be a local requirement and are not universally mandatory. For non-mandatory documents, the number of copies and specific documents required will vary according to local HREC policy.

**24.8.** Photocopying and collating the required number of copies of documents is the responsibility of the applicant. If bundles are submitted uncollated, they will be deemed to be invalid until collated by the applicant.

**24.9.** Every application must contain a study synopsis or protocol. The HREA is not the protocol. The study synopsis or protocol must be consistent with the information the applicant enters on to the HREA.

**24.10.** For multi-site studies, clean master copies of patient informed consent forms should be uploaded to the HREA for HREC review. Site specific tracked versions should be uploaded into the SSA for governance review.

**24.11.** Applications requiring full HREC review must be validated (marked as Ready for review) before allocation to a HREC meeting. See SOP 25 Validation - detailed process.

**24.12.** For studies being reviewed at a HREC meeting all applications must be received by the HREC Administrator by 12:00 midday on closing day unless otherwise negotiated with the HREC Administrator.

**24.13.** Where possible, applications will be forwarded by the HREC Administrator to the reviewer/s at least 10 business days prior to the meeting of the scientific sub-committee (if applicable), or at least 10 business days prior to the HREC meeting at which the application will be reviewed by the HREC.

**24.14.** For applications not requiring full HREC review the period of 60 clock days within which an ethics decision must be given, begins when a valid application is received by the reviewing body.

**Revision of applications following submission**

**24.15.** Once an application has been validated and is ready for review, the applicant will be unable to make any revisions prior to the review by the scientific sub-committee, external expert reviewers or HREC meeting.

**24.16.** If the applicant considers it necessary to revise the application or the supporting documentation prior to review by the HREC, the applicant could withdraw the application on ERM and re-submit the application at a later date. Alternatively, the applicant may ask the HREC Administrator to unlock the form by selecting Further information Requested and the applicant can make the corrections and resubmit as another version rather than restarting the application. The appropriate option can be determined by speaking with the applicant.

**24.17.** If it is considered necessary to make minor revisions (e.g., correction of typographical errors etc) to the supporting documentation after review by the HREC but before a final ethics decision has been given, these may also be included in the applicant's response to a request made by the HREC for further information.

**24.18.** The changes should be clearly highlighted in the updated documents using the Microsoft Word Track Changes function or similar, and the relevant documents given new version numbers and dates. An accompanying cover letter must be provided explaining clearly what the changes are and why these have been made.

- These updated documents are to be uploaded into ERM by the applicant and the application re-submitted to enable the HREC Administrator to record the HREC Chair or HRECs decision upon review of the updated documentation.

**24.19.** At the discretion of the HREC, the revisions may then be reviewed in accordance with the procedures agreed for considering further information from the applicant.

**24.20.** If the HREC Chair considers the proposed revisions to be significant and unrelated to the matters raised by the HREC in the ethics review, the applicant may be advised to withdraw the application and re-submit as a new application. Alternatively, the revisions may be submitted to the HREC in-between meetings or at the next HREC meeting.

**24.21.** For revisions made after a final ethics decision has been given, refer to the procedures for review of amendments.

**Withdrawal of applications**

**24.22.** The applicant can withdraw an application at any time. It is preferred that the applicant withdraw the application in writing as well as selecting the action in ERM. A withdrawal letter should then be uploaded into ERM under the documents tab by the HREC Administrator.

**24.23.** The status of the application should be marked Withdrawn on ERM and provided the file is in order, it can be closed and archived. If the applicant wishes to re-submit the application later, it should be treated as a new submission.

**24.24.** If the applicant wishes to re-submit to a different HREC, the applicant must notify the new HREC of the withdrawn review from the original HREC.

# 25. HREC 025: Validation - detailed process

**25.1.** It is the responsibility of the CPI or Site PI to ensure that the completed HREA contains all of the essential elements when submitted to the HREC. This includes all attachments as listed in the Local HREC Checklist, if required. An application is accepted as valid if it meets all of the following criteria:

a) All questions and sections in the HREA have been completed.

b) All supporting documents are uploaded. All project documents require a document identifier: version numbers, document date (dd/mm/yyyy), page numbers and logos where appropriate, which must be included in the header and/or footer.

c) The application has been signed by the CPI (multi-centre applications) or PI (single site applications), and

d) If hard copies are required, all documentation has been collated into bundles, with each bundle containing a copy of all required paperwork (as per local HREC requirements). It is the responsibility of the CPI or Site PI to ensure that the completed HREA contains all of the essential elements when submitted to the HREC. This includes all attachments as listed in the Local HREC Checklist, if required.

**25.2.** Regarding the signatures of the investigators, only the signature of the CPI (for multi-centre research) or PI (in the case of single site research) is required on the HREA, unless the applicant is a student, in which case, the signature of the supervisor is also required. ERM supports electronic signatures. The signature of the CPI or PI may also be accepted by a HREC in email or letter format by attaching the document to the HREA via ERM.

**25.3.** The Head of Department is not required to sign the HREA as they will sign the Site Specific Assessment form (SSA).

**25.4.** Queensland Health accepts electronic signatures in research applications. More information can be found here: Electronic Approval Department of Health Guideline QH-GDL-449-1:2017

**25.5.** An application is invalid if:

a) Major discrepancies are present e.g., the submission is not on the appropriate application form (HREA) or is incomplete.
b) The required supporting documentation (such as protocol, Information Sheet and Consent form, questionnaires and other tools) has not been uploaded and submitted with the application.
c) The documentation is not signed by all relevant parties either electronically or via wet ink signature, or with other uploaded documents.
d) The application is so poorly written that it is deemed by the HREC Administrator and /or HREC Chair to be invalid and cannot be reviewed by the HREC until it has been re-written, undergone peer review where required and been re-submitted.
e) If hard copies are required, submitted documents have not been collated into bundles with one copy of each document in each bundle (as advised on the local HREC checklist).

**25.6.** Applications are marked as either valid (ready for review) or Invalid in ERM. For guidance on this process, view the ERM manual (found in the help tab).

**25.7.** Invalid applications will have a timeline note placed in ERM or if applicable explanatory evidence uploaded to review documents to outline why the application is deemed to be invalid by the HREC Administrator and/or HREC Chair.

# 26. HREC 026: Research that may be exempted from HREC review

**26.1.** In determining whether a research project is exempt from ethics review HRECs must comply with the National Statement.

Shared or banked data or information that is stored in a form that can identify individuals can sometimes be used in research that qualifies as minimal or low risk research; however, it cannot be used in research that is exempt from ethics review.

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

- Consult the National Statement and
- Provide an outline of the project in writing to the HREC Chair justifying why they are seeking exemption from HREC review.

# 27. HREC 027: Exceptional circumstances review

**27.1.** 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 urgent threat to public health. There could also be a need to capitalise on a unique opportunity for significant research where there is only a limited time to consider participation.

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

**27.3.** The HREC review for all exceptional circumstance studies will be for a single site only, and applications must be submitted via ERM for processing.

**27.4.** Applications submitted for review under exceptional circumstances should contain:

a) A completed ERM version of the HREA or another format if time does not allow for the ERM HREA to be completed.
b) Study protocol and supporting documentation and
c) A written request for an exceptional circumstance review, which explains the reason and justification for requesting exceptional review.

**27.5.** The application will be checked by the HREC Administrator to determine whether the submission is either valid or invalid and the HREC Chair decides whether it qualifies for exceptional review. Please refer to above section Validation of applications.

**27.6.** The application will be reviewed by the HREC Chair and one or more HREC member/s out of session. Wherever possible the application should be reviewed by a quorum of HREC members. If not, at a minimum one of these reviewers should be a person who bring a broader community or consumer perspective or other member not affiliated with the reviewing institution. The reviewers will be given the opportunity to seek clarification from the applicant or from other HREC members, if required, prior to making a decision.

**27.7.** If the decision of the HREC Chair and additional HREC member/s is unanimous that the application can be granted HREC approval then the local RGO may decide to waive the requirement to complete the SSA and document CE authorisation an alternative way.

**27.8.** If there is disagreement between the HREC Chair and the additional HREC member/s, the protocol will not receive exceptional circumstance review and will be reviewed by the full HREC.

# 28. HREC 028: Requests for retrospective research approvals

**28.1.** The term retrospective approval means research that has been conducted without necessary approvals in place prior to starting the research. Queensland Health HRECs will not provide retrospective approval of such research.

**28.2.** If a HREC Administrator is presented with a request for retrospective approval of research work already completed without necessary approvals in place prior to starting the research, the following advice should be given to the researcher:

c) The HREC is unable to provide a retrospective approval for a project that has not been presented to an ethics committee for review or approval prior to the research taking place.

d) An Approval Letter cannot and will not be issued. However, the HREC Chair can agree to provide a letter acknowledging the work that was done (once they have been provided with, and reviewed the study plan, methodology and outcomes), and state that it appears to comply with the requirements of the National Statement but was undertaken without HREC approval in place.

e) This process does not give a retrospective HREC approval but gives an HREC Acknowledgment of a completed project. It is up to the publishers as to whether or not that is acceptable.

**28.3.** Presentation of un-consented confidential information at conferences or in journals.

HRECs will often be asked to provide an approval for presentation of un-consented confidential information for conference presentations or for publication in professional journals. If confidential information is disclosed without the consent of the person whom the data relates, an application under the PHA may be made so there is a legal permission to disclose confidential information. A letter from the HREC must be generated noting the appropriate approvals are in place and a waiver of consent has been granted.

# 29. HREC 029: Registries and Databanks

**Starting a registry**

**29.1.** All new applications for ethics review are to be submitted using the ERM version of the HREA accessed via https://au.forms.ethicalreviewmanager.com/.

**29.2.** The processing of the application will depend on the level of risk associated with the registry. For example, a registry study that follows, for ten years, the progress of patients who have received a particular type of prosthesis would be considered lower risk. However, a registry that lists patients with a particular disease may be considered as higher risk and may need to be reviewed by the full HREC.

**29.3.** If the registry is multi-centre, it may be reviewed as Low Risk Research via the institutions Lower Risk review pathway and must be submitted on a HREA.

**29.4.** For prospective entry of data into a registry, an Information Sheet and Consent form may be required.

**29.5.** If the researcher wishes to access patient data retrospectively to enter into the registry, consent will need to be obtained either from the patient involved, or via another legal permission such as the PHA application process prior to the collection and entry of the data into the registry.

**Accessing data for the purposes of research from an already existing registry or databank**

**29.6.** If a researcher wishes to access data from an already existing registry or databank, the HREA application form is required.

**29.7.** If the registry or databank is from another research project, permission from the PI (or Data Custodian) of the original study is required.

**29.8.** The Information Sheet and Consent form that was originally presented to the participants to allow entry of their data into the registry or databank needs to be checked to see if consent was given for their data to be used for future research projects and if there were any limitations placed on that.

**29.9.** If consent has not been obtained to enter data into the databank or registry, or if original consent did not allow for data to be used for research purposes, other legal permissions must be identified e.g. PHA application or HHB Act permissions to allow disclosure of unconsented potentially identifiable confidential health information for the purposes of research.

**29.10.** Only an HREC may grant waiver of consent for research using personal information in medical research, or personal health information.

# 30. HREC 030: Research involving Aboriginal and Torres Strait Islander peoples

**30.1.** When completing the HREA researchers must consult *Ethical conduct in research with Aboriginal and Torres Strait Islander Peoples and communities: Guidelines for researchers and stakeholders* in accordance with Chapter 4.7 of the National Statement.

**30.2.** Other documents that might provide useful guidance for researchers are *Keeping Research on Track II* and the *Guidelines for Ethical Research in Australian Indigenous Studies* (Australian Institute of Aboriginal and Torres Strait Islander Studies 2012).

**30.3.** HRECs are also required to apply the *Ethical conduct in research with Aboriginal and Torres Strait Islander Peoples and communities: Guidelines for researchers and stakeholders* as the basis for assessing proposals for health research with Aboriginal and Torres Strait Islander participation.

**30.4.** In applying Sections 1 and 2 of the National Statement, *researchers from other disciplines, HRECs and other ethical review bodies may also find the Ethical conduct in research with Aboriginal and Torres Strait Islander Peoples and communities: Guidelines for researchers and stakeholders* informative.

**30.5.** Research to which this chapter applies must be reviewed and approved by a HREC rather than by one of the other processes of ethical review described in paragraphs 5.1.15 - 5.1.17 of the National Statement. The HREC process must have included assessment by or advice from:

a) people who have networks with Aboriginal and Torres Strait Islander Peoples and/or knowledge of research with Aboriginal and Torres Strait Islander Peoples; and
b) people familiar with the culture and practices of the Aboriginal and Torres Strait Islander People with whom participation in the research will be discussed.

**30.6.** In Queensland, researchers should ensure appropriate community input, for example through the Queensland Aboriginal and Islander Health Council (QAIHC).

**30.7.** There is no NHMRC certification category in the multi-centre review process for the review of multi-centre research involving Aboriginal or Torres Strait Islander Peoples.

**30.8.** Multi-centre research involving Aboriginal or Torres Strait Islander Peoples can be reviewed by any Registered HREC using the guidance provided in the National Statement.

**30.9.** On receipt of a research application involving Aboriginal or Torres Strait Islander Peoples, the HREC Administrator must consult with the HREC Chair to determine how the HREC review processes will include assessment or from whom advice will be sought.

# 31. HREC 031: Research involving access to coronial material

**31.1.** 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. This also applies to clinical research studies where there is a component involving coronial material. In this context, coronial material includes everything derived from or related to coronial autopsies and investigations, for example:

a) tissues from coronial autopsies
b) microscope slides

c) wax blocks
d) blood samples
e) photographs
f) medical imaging
g) autopsy reports, and
h) other documents and data relating to coronial autopsies.

**31.2.** The use of material from coronial autopsies for research requires the approval of the State Coroner. If the research involves access to coronial documents, approval as a genuine researcher under section 53 of the *Coroners Act 2003* (Qld) is also required. These approvals are subject to reviews by an ethics committee whose membership includes representatives of the State Coroner. This is facilitated through the FSS Research Office.

**31.3.** Fees may be levied by Forensic and Scientific Services to recover costs associated with ethics review and monitoring of research projects from applicants external to Queensland Health.

**31.4.** All costs associated with seeking coronial and next of kin consent and retention of autopsy tissues for approved studies are required to be funded by the relevant project. For further information, email enquiries can be directed to FSS_HEC@health.qld.gov.au

# 32. HREC 032: Impaired capacity of adult to consent to research participation

**32.1.** Where a person is over the legal age of consent but lacks capacity and is unable to give informed consent to participate in research, the researcher must make a written application to Queensland Civil and Administrative Tribunal (QCAT) (except where there is a direction in an Advance Health Directive relating to special medical research or experimental health research).

**32.2.** The process will depend on whether the research is 'clinical research' or 'special medical research or experimental health research', defined as:

| | | | |
|---|---|---|---|
| a) | 'Clinical research' is medical research intended to diagnose, maintain or treat a condition affecting the participants in the research or a trial of drugs, devices, biologicals or techniques involving the carrying out of health care that may include giving placebos to some of the participants in the trial. | Link | Ch 5 Pt 3A of the *Guardianship and Administration Act 2000* (Qld) |
| b) | 'Special medical research or experimental health research' is medical research or experimental health care relating to a condition the adult has or to which the adult has a significant risk of being exposed, or medical research or experimental | Link | Schedule 2, Part 2 of the *Guardianship and Administration Act 2000* (Qld) |

health care intended to gain knowledge that can be used in the diagnosis, maintenance or treatment of a condition the adult has or has had.
'Special medical research or experimental health research' does not include psychological research or approved clinical research.

**Clinical research**

**32.3.** A clinical research project that will involve a person with impaired capacity to consent must be submitted to the Queensland Civil and Administrative Tribunal (QCAT) for approval. Section 74C of the *Guardianship and Administration Act 2000* (Qld) sets out the minimum requirements for QCAT to approve clinical research. It is a precondition to QCAT approval that the research be approved by a HREC.

Once clinical research has been approved by QCAT (approved clinical research), the person's usual substitute decision-maker may consent for the person to participate in the research.

**Special medical research and experimental health care**

**32.4.** An adult may make directions for future special medical research or experimental health care in an Advance Health Directive (section 8(1)(b) of the *Guardianship and Administration Act 2000* (Qld)). If there is no relevant direction in an Advance Health Directive, QCAT must consent for an adult without capacity to participate.

**32.5.** Section 72(2) of the *Guardianship and Administration Act 2000* (Qld) sets out how QCAT may consent, for an adult with impaired capacity for the special health matter concerned, to the adult's participat**ion** in special medical research or experimental health care. In summary, QCAT must be satisfied:

a) that prior HREC approval is in place
b) the risk and inconvenience to the adult and their quality is small
c) the special medical research or experimental health care may result in significant benefit to the adult or other person with the condition
d) the special medical research or experimental health care cannot reasonably be carried out without a person who has or has had the condition taking part
e) the special medical research or experimental health care will not unduly interfere with the adult's privacy.

**32.6.** In addition to ethics approval, where the research requires a Queensland Health employee 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. For more information, please refer to "Guideline for researchers – disclosure of confidential information".

**32.7.** The researcher must have the clinical training to determine if a potential participant has the capacity to provide consent to participate in the research or the consenting process

should be conducted by a suitably qualified person who can make the determination.

**32.8.** For more information, please refer to https://www.qcat.qld.gov.au/matter-types/clinical-research

# 33. HREC 033: Research involving children

**33.1.** 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

**33.2.** If the information is related to a child, the parent or guardian must consent if the child is not a "Gillick competent child" i.e., if the health professional believes the child is of sufficient age and mental and emotional maturity to understand the nature of consenting to the disclosure via the completion of a consent form. If the child is not capable of consent, then the HREC may require an assent form, or the Health Professional must reasonably believe the disclosure of the information is in the child's best interest.

**33.3.** Section 21C of the *Transplantation and Anatomy Act 1979* (Qld) provides that the removal of tissue (including blood) from a child's body is authorised if it is done for the purpose of approved research, consent is given as required under the National Statement, and one or more of the following applies:

a) the approved research is for benefit of the child.
b) the removal of tissue occurs during a procedure that is for the benefit of the child and a medical practitioner is satisfied the removal of the tissue for approved research is not likely to prejudice the health of the child or
c) a medical practitioner is satisfied the removal of tissue will involve minimal/low risk of harm and minimal discomfort to the child.

**33.4.** 'Approved research' means research approved by a HREC in accordance with the Australian Code and the National Statement. This means that a person can only consent to the removal of tissue for research purposes where the research that has been approved by a HREC.

# 34. HREC 034: Research involving biospecimens

**34.1.** '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).

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

**34.3.** 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.

**34.4.** If the research involves collection and storage of tissue from Children, please refer to SOP HREC 033: Research involving children.

**34.5.** Applications to create a biobank must only be considered by the full HREC.

# 35. HREC 035: Quality activities

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

**35.2.** A HREC will frequently be presented with a project that is clearly a QA project. However, undertaking a QA project does not require HREC approval even if an ethics opinion is sought. QA projects should be registered as per the institution's Clinical Governance process.

**35.3.** If an ethics opinion is sought, then local institutional practice may include delegating responsibility to:

a) A QA/low-risk committee.
b) A sub-committee of the HREC.
c) The HREC Chair or appropriate HREC member(s) or HREC Executive as delegated by the HREC Chair, or
d) Another appropriate committee or individual involved in/responsible for clinical governance.

**35.4.** If the delegated responsibility sits with a member of the HREC, then the applicant should be advised to liaise with the HREC administrators to prepare the documentation required, but as a minimum, a cover letter, description of the project and project documentation and evidence of patient consent (if applicable) that has been registered as part of the institution's Clinical Governance process, along with the intended article for publication should be submitted for review by the HREC Chair.

**35.5.** The project is submitted on ERM by the applicant and given an ERM Identification number but should be categorised as a QA project.

**35.6.** The HREC Chair or reviewing delegate body will review the submitted documentation and do one of the following:

a) Appraise the project and issue a letter stating that it is a non-research project and does not require full HREC review for an ethical opinion to be given, or

b) Appraise the project and require it to be submitted for review by the HREC or Lower Risk Committee. If it is considered that the project is not a QA, or if parts of the project are to be conducted outside the scope of a QA, a HREA must be completed and submitted with the application.

# 36. HREC 036: Consent: Waiver and opt-out

**36.1.** Please note that the term 'deferred' or 'delayed' consent is not supported by the National Statement or by Queensland Health. See Research involving patients who are unable to give consent | Queensland Health

**Granting a waiver of consent**

**36.2.** In some cases, an applicant may apply to the HREC for approval of a waiver of consent for use of confidential information for research.

**36.3.** 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). In summary, a HREC must be satisfied:

a) Involvement in the research carries no more than low risk to participants.
b) The benefits justify any risk of harm associated with not seeking consent.
c) It is impracticable to obtain consent.
d) There is no known or likely reason for thinking participants would not have consented if they had been asked.
e) There is sufficient protection of privacy.
f) There is an adequate plan to protect the confidentiality of data.
g) In case the results have significance for the participants' welfare there is, where practicable, a plan for making information arising from the research available to them (e.g. via a disease-specific website or regional news media).
h) The possibility of commercial exploitation of derivatives of the data or tissue will not deprive the participants of any financial benefits to which they would be entitle and

i) The waiver is not prohibited by law.

**36.4.** Only a full HREC may grant a waiver of consent for research using personal information in medical research, or personal health information.
A lower risk sub-committee cannot grant a waiver of consent. Lower risk projects requiring access to identifiable or potentially re-identifiable confidential health information without consent must be reviewed by a full HREC (noting the recommendation from a subcommittee can be given to a full HREC for ratification).

**36.5.** The decision to grant a waiver of consent must be recorded in the HREC approval letter and meeting minutes. The HREC approval letter should state if the Queensland Privacy Guidelines (if applicable as they are currently under development) or section 95 and 95A of the *Privacy Act 1988* has been considered when granting a waiver of consent for an application, this must also be recorded in the meeting minutes and HREC approval letter.

**36.6.** Examples of research that may qualify for consideration of a waiver of consent (from the individual) are:

a) Accessing potentially identifiable data from data sets.
b) Accessing patient records.
c) Accessing tissue from tissue banks, or
d) The research involves no more than low risk to participants.

However the conditions outlined in the National Statement 2.3.10 still need to be met.

**Obtaining consent from a proxy/substitute or legally authorised representative**

**36.7.** Where a research project includes participants, who are not competent – either temporarily or permanently (as determined by a clinician) – to consent to their participation in a research project, the application must include an Information Sheet and Consent form directed to the Legally Authorised Representative. This is irrespective of the type of research being undertaken.

**36.8.** Where the project includes experimental treatment, the researcher must also apply to QCAT after obtaining HREC Approval for the project has been obtained (see HREC 032: Impaired capacity of adult to consent to research participation).

**Conditions for the granting of an Opt-Out Approach**

**36.9.** The Opt-Out approach is a method used in the recruitment of participants into research where information is provided to the potential participant regarding the research and their involvement and where their participation is presumed unless they take action to decline to participate. An Opt-Out approach is not the same as consent. In some instances, to do certain things a permission must be identified in legislation for example, disclosure of confidential information in the HHB Act or PH Act. If an opt-out approach is being used in the research that is not considered a legal permission under those Acts.

**36.10.** Researchers may request an Opt-Out approach to consent. This request must be made using a HREA.

**36.11.** The application must only be considered by the full HREC.

**36.12.** Potential research participants must be given a comprehensive Information Sheet, which clearly outlines the Opt-Out options. The process must be clearly written up in the participants' medical notes.

**36.13.** Applicants must explain in the application how, if an Opt-Out form is not returned, they will differentiate between opting into the project and apathy or misunderstanding of the process by potential research participants.

**36.14.** If an Opt-Out consent process is used, HHB Act permissions may apply or a PHA application may need to be made for legal permission as confidential health information will be used without the consent of the person to whom the data relates. However, the applicant must apply for a waiver of consent via a HREC.

**Witness to the consent**

**36.15.** Generally, it is not a requirement for a Consent form to be countersigned by a witness unless the consent is from:

a) A person with an impairment, disability or illness that is temporary or episodic at a time when the condition does not interfere with the person's capacity to consent, or

b) A child who requires adult or guardian oversight or consent in conjunction with the child's consent.

**36.16.** ICH GCP 4.8.9 provides the following guidance for the requirements for a witness to a consent:

(a) If a subject or legally acceptable representative is unable to read, an impartial witness should be present during the entire informed consent discussion.

(b) After the written informed Consent form and any other written information to be provided to subjects is read and explained to the subject or the subject's legally acceptable representative, and after the subject or the subject's legally acceptable representative has orally consented to the subject's participation in the trial and, if capable of doing so, has signed and personally dated the informed Consent form, the witness should sign and personally date the Consent form.

(c) By signing the Consent form, the witness attests that the information in the Consent form and any other written information provided was accurately explained to, and apparently understood by, the subject or the subject's legally acceptable representative, and that informed consent was freely given by the subject or the subject's legally acceptable representative.

(d) Where the impairment, disability or illness is temporary or episodic, an attempt should be made to seek consent at a time when the condition does not interfere with the person's capacity to give consent (refer to the National Statement, section 4.5.6). In these circumstances, the consent should be witnessed by a

person who has the capacity to understand the merits, risks and procedures of the research, is independent of the research team and, where possible, knows the participant and is familiar with his or her condition.

**36.17.** It must be understood that the witness is not simply witnessing the signing of the Consent form but is attesting to the entire consenting process – that the information in the Information Sheet and Consent form and any other written information provided was accurately explained to, and apparently understood by, the participant or their legally authorised representative and that informed consent was freely given by the participant or their legally authorised representative.

# 37. HREC 037: Guidelines for disclosure of Confidential Information

**37.1.** **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 PHA,
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 or the protection or promotion of public health (that is, indirect possible future connections are insufficient).

**37.2.** The use of the authority to disclose in section 150(a) of the HHB Act is subject to numerous caveats and conditions. 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.

**37.3.** 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.

**37.4.** Where PHA approval is required, a PHA application must be completed and submitted to ORI for consideration and approval prior to Queensland Health governance authorisation being granted (if applicable). For more information: Using confidential information in research | Queensland Health

**37.5.** All research projects requesting a waiver of consent must be reviewed by a HREC. HRECs may provide a waiver of consent, in accordance with section 2.3 of the National Statement.

**37.6.** HRECs need to consider if the proposed research study conduct complies with the Queensland Privacy Guidelines (if applicable) and section 95 and 95A of the Privacy Act. For more information: Guidelines approved under section 95A of the Privacy Act 1988, NHMRC.

# 38. HREC 038: Possible Additional Requirements for approved projects including Indemnity and Insurance

**Indemnity**

**38.1.** The degree of indemnity is commensurate with the level of risk associated with the project.

**Commercially sponsored research**

**38.2.** Institutions must be satisfied that sponsors of clinical trials have indemnity, insurance and compensation arrangements in accordance with applicable regulatory requirements. For commercially sponsored Clinical Trials, the Medicines Australia Form of Indemnity – HREC Review Only must be submitted to the HREC. All sites for which the Reviewing HREC is providing HREC review must be listed in the Form of Indemnity – HREC Review Only. A Certificate of Currency must accompany this Form of Indemnity.

**38.3.** The Medicines Australia Form of Indemnity – Standard may be used when there is only one site participating in the commercially sponsored study, and the Reviewing HREC and the site are from the same institution. However, if an additional site is added to the project, under the same HREC jurisdiction, the Form of Indemnity – HREC Review Only must be completed and submitted for execution, and the new site must have its own Form of Indemnity – Standard. The original Form of Indemnity – Standard will remain valid for the site that is at the same institution as the Reviewing HREC.

**38.4.** The HREC Administrator should liaise with the site RGO to determine local processes for CE execution of the Forms of Indemnity.

**38.5.** The HREC Approval letter should not be released until the indemnity form that covers the HREC has been executed.

**38.6.** For more information, refer to Department of Health Research Management Policy V3 (11 August 2022) (for the department) and the Research Ethics and Governance Health Service Directive (for HHSs).

**Investigator initiated research**

**HREC Indemnity:**

**38.7.** When assessing an investigator-initiated research project, indemnification of the HREC is provided by the Sponsor of the project or their employer (Queensland Health).

**38.8.** For Clinical Trials where Queensland Health are acting as Sponsor, details of the trial must be included within the Professional Indemnity register.

**38.9.** Each institution is responsible for determining its own level of acceptable risk and the indemnification requirements, for the HREC, for that level of risk.

**International research operating under a research grant**

**38.10.** Indemnification requirements as for investigator-initiated research.

**Insurance**

**38.11.** Generally, insurance is the domain of the RGO. However, the Form of Indemnity – HREC Review Only must be accompanied by an appropriate Certificate of Currency for commercially sponsored studies.

**38.12.** It is preferred that the insurance company has a representative office in Australia to enable rapid review and settling of any claims.

**38.13.** For sponsored clinical trials, the Sponsor or CRO is to indemnify the Department / HHS against claims by patients arising from the study in terms consistent with the Medicines Australia standard forms of indemnity: http://medicinesaustralia.com.au/issues-information/clinical-trials/indemity-and-compensationguidelines/.

**38.14.** Required insurance:

a) Clinical Trial/Product Liability insurance for an amount not less than $20 million AUD per claim:
b) Public liability insurance is required for an amount not less than $10 million AUD per claim
c) Professional indemnity insurance is required for an amount not less than $10 million AUD per claim

**38.15.** Workers' compensation insurance in required accordance with applicable legislation.

**38.16.** All insurance certificates must be valid at the time of submission for Research Governance review – with the exception of the insurance certificate submitted with the Form of Indemnity – HREC Review Only which must be valid on submission to the HREC.

# 39. HREC 039: Amendments to research post HREC approval

**General guidance**

**39.1.** Researchers are required to obtain ethics approval and research governance authorisation before implementing any amendment to a previously approved study.

**39.2.** Where a site specific amendment has no impact on the ethics acceptability of the study, the HREC review is bypassed (for example only when changes are to site contracts and participating site staff other than the PI).

**Processing of amendments to a research project**

**39.3.** The Site PI (or CPI for multi-centre studies) is required to submit amendments for approval to the Reviewing HREC.

**39.4.** Amendments should be outlined in a cover letter from the PI/CPI, stating the changes and reasons for changes, and accompanied by all relevant updated documents (which have been uploaded to ERM by the PI/CPI). Updated documents should be uploaded in two forms – one with tracked changes and one clean copy. Hard copies of the cover letter and all relevant updated documents may need to be submitted to the HREC Administrator, depending on local HREC procedure.

**39.5.** The HREC Chair will review all amendments and will use his/her discretion to refer the amendment to the next scheduled HREC meeting for review or to consider it outside of the HREC meeting. Amendments should be referred to the full HREC when they impact the continued ethical acceptability of the study. The HREC Chair will be the spokesperson for the amendment. All amendment decisions must be noted on the agenda for the next HREC meeting.

**39.6.** The HREC will review the amendment request and may require further clarification or information regarding the amendment prior to granting approval.

**39.7.** The HREC/HREC Chair will notify the PI/CPI in writing of its decision.

**39.8.** For commercially sponsored research, an amendment review fee may be charged.

**Amendments for urgent safety measures**

**39.9.** Please refer to the NHMRC Safety monitoring and reporting in clinical trials involving therapeutic goods: Risk-based management and monitoring of Clinical Trials involving therapeutic goods Reporting of Serious Breaches of Good Clinical Practice (GCP) or the Protocol for Trials Involving Therapeutic Goods Data Safety Monitoring Boards.

**Updated safety information post HREC approval**

**39.10.** The National Statement section 5.4.15 lists circumstances where it may be unethical for a researcher to continue a trial. This includes if:

a) There are or have been substantial deviations from the trial protocol.
b) Adverse-effects of unexpected type, severity or frequency are encountered or
c) As the trial progresses, the continuation of the trial would disadvantage some of the participants as determined by the researchers or others monitoring the trial.

The HREC should inform the PI/CPI if they become aware of such circumstances.

**39.11.** In this instance, the researcher, institution and (where possible) participants should be informed of the withdrawal and the institution must see that the researcher promptly suspends the research and makes arrangements to meet the needs of participants. The study will be logged in ERM as having been terminated. A note explaining the reason for the termination may be made in ERM in the project's account.

**Amendments requiring submission of a new application**

**39.12.** Where a proposed amendment would fundamentally alter the nature of the research and the extent of the involvement of, or risk to, existing and/or potential participants, the HREC may give a Not Approved decision and request submission of a new application for full ethics review.

**39.13.** Examples might be where the proposed amendment involves:

a) A change in the primary purpose or objective of the research, such as introduction of additional genetic sub-studies.
b) A substantial change in research methodology.
c) Introduction of new classes of investigations or other interventions (rather than simply rescheduling or modifying those already approved).
d) Recruitment of a new type of participant (especially if these would be regarded as being from vulnerable groups) or
e) Extension of a drug trial into an open-label trial, i.e. all patients to receive study drug (this would be considered to be an entirely new study).

**Decision regarding amendments**

**39.14.** The decision reached will follow the same process as for new applications. For more information, refer to 'HREC 015: Decisions available to the HREC'.

**Expansion of a research study to an additional site/s**

**Single site studies**

**39.15.** Where a single site study is to be extended to additional site/s, the role of the CPI will be negotiated between all PIs and the Sponsor, if applicable.

**39.16.** If the original Reviewing HREC is not certified to review multi-centre research in the study field, the CPI will be required to re-submit the study to a Certified HREC for review.

**39.17.** If the original Reviewing HREC is certified to review multi-centre research in the study field, the CPI or study contact must contact the HREC Administrator to discuss the addition of the new site, and the change of the study from single site to multi-centre.

**39.18.** If the HREC Chair agrees to accept the additional site and take on monitoring responsibilities for a multi-centre study, the CPI will submit an amendment to the original Reviewing HREC.

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

**39.20.** If the HREC Chair does not agree to accept the additional site and amend the study from single site to multi-centre, the applicant must organise for the study to be allocated to a new Reviewing HREC as a multi-centre study.

**39.21.** The original HREC will continue to retain responsibility for the original site until such time as the new Reviewing HREC assumes monitoring responsibility for all sites under their jurisdiction. When this occurs, the original HREC should change the study on ERM as Withdrawn by Researcher and insert appropriate comments into the Notes section for that study in ERM.

**39.22.** It is the responsibility of the CPI to notify the new PIs when HREC Approval has been granted.

**39.23.** The research must not commence at each additional site until each respective site/HHS has granted authorisation.

**39.24.** For those studies conducted under CTN/CTA conditions, the TGA must be notified of the new site/s by completion of the appropriate paperwork by the Sponsor.

**Multi-centre studies**

**39.25.** Where a multi-centre study has been approved by a Certified HREC in the study field and is to be extended to include additional site/s, the CPI will submit an amendment to the Reviewing HREC to notify the Reviewing HREC of the additional sites. This ensures that the Reviewing HREC has the relevant information to correctly monitor the study.

**39.26.** The Reviewing HREC will notify the CPI once HREC approval for the additional sites is granted.

**39.27.** The research must not commence at any additional site until each respective site/HHS has granted authorisation.

**39.28.** For those studies conducted under CTN/CTA conditions, the TGA must be notified of the new site/s by completion of the appropriate paperwork by the Sponsor.

**Adding the first State Specific Module site to an approved study**

**39.29.** If a research project has already been reviewed and approved, and no State Specific Module sites were included in the original application, an application to include a State Specific Module site must be made as an amendment and reviewed by a full HREC.

**39.30.** The amendment application must also be submitted with the State Specific Module, which is recommended to have been completed by the PI at the first relevant site. The State Specific Module is submitted with the HREA to the Reviewing HREC.

**39.31.** The Reviewing HREC will consider this protocol amendment in the usual manner, refer to section 3.4.

**Additional documentation required when adding a new site to an already approved project**

**39.32.** When adding additional sites to an already approved project, in addition to the requirements outlined above, the following documents must accompany the application:

a) the CV of PIs at the new site/s,
b) Form of Indemnity – HREC Review Only (commercially sponsored trials only) listing all participating sites for which the HREC has monitoring responsibility and
c) Certificate of Currency confirming clinical trial insurance where relevant.

# 40. HREC 040: Lower or higher risk research review

**40.1.** The National Statement recognises that human research involves a wide range of activities that have variable risks and potential benefits. It establishes different levels of ethics review, though a continuum-based model from minimal risk to high risk, falling under two broad categories: lower risk and higher risk.

**40.2.** Researchers, institutions and HRECs are required to determine the existence, likelihood and severity of these risks based on the research methodology and design, participant population and research activity.

**40.3.** A low and minimal risk project can be reviewed by a low and minimal risk pathway, however the decision to grant a waiver of consent must be ratified by a full HREC committee.

**Procedure for review of research which is exempt from a full HREC review (Lower Risk)**

**All studies**

**40.4.** Institutions may establish non-HREC levels of ethics review for lower risk research projects. The levels of ethics review may include, but need not be limited to:

a) Review or assessment at departmental level by the head of department.
b) Review or assessment by a departmental committee of peers (with or without external or independent members).
c) Delegated review with reporting to a HREC or
d) Review by a sub-committee of a HREC.

**40.5.** If the institutional HREC has been certified by the NHMRC to review multi-centre research, and if the SOPs and Terms of Reference for the lower risk review process were assessed as part of the NHMRC Certification process, and if the Lower Risk Sub-Committee reports

directly to the institutional HREC, then the Lower Risk Committee is able to review multi-centre low or minimal risk research projects. The outcome of the Lower Risk Committee must be fully documented in the HREC agenda and minutes.

**40.6.** A Lower Risk Sub-Committee cannot review multi-centre lower risk research if:

a) The institutional lower risk review process was not reviewed by the NHMRC at the time of HREC certification.

b) The institutional lower risk review process has been changed since NHMRC certification was granted to the HREC and the NHMRC has not accepted the change.

c) The Lower Risk Committee stands alone and does not advise the HREC of their recommendations.

**40.7.** All lower risk research projects must be logged in ERM using a HREA. Non-HREC meetings can be created on ERM in order to allocate lower risk studies for review, according to institutional processes.

**40.8.** It is the institution's responsibility to determine which level of ethics review process is implemented for lower risk research and to create site specific SOPs relating to lower risk research review processes as appropriate.

**40.9.** For all lower risk research studies, the HREA (accessed via ERM) must be completed.

**40.10.** Researchers should be encouraged to contact the local HREC/RGO to gain advice of whether the project can be reviewed by a non-HREC process.

**40.11.** If the Reviewing HREC considers that the application poses more than low risk (even if unlikely), the application will not be eligible to be reviewed by an Lower Risk sub-committee and will be reviewed at a full meeting of the HREC (according to local requirements).

**Multi-centre Lower Risk studies**

**40.12.** All multi-centre lower risk applications will be submitted to a Certified HREC under the NMA model (or other MOU) and a HREA must be completed.

**40.13.** If the requirements for lower risk review in this SOP are not met, then the multi-centre lower risk study must be reviewed by the full HREC.

**40.14.** Research Governance processes will always need to be completed and submitted to the RGO at each participating site.

# 41. HREC 041: HREC monitoring of research granted institutional authorisation

**General guidance**

**41.1.** All research which has received institutional HREC approval and governance authorisation should be monitored. While it is the responsibility of the HREC to ensure monitoring of research approved by them occurs, this is not always the case.

**41.2.** In the case of commercially sponsored clinical trials, they are normally monitored by the sponsor's representative. However, if this is not the case it is the responsibility of the HREC to ensure monitoring of these trials occurs.

**41.3.** In the case of Investigator initiated research, it is the responsibility of the HREC to ensure monitoring of these trials occurs.

**41.4.** To allow monitoring to occur, the HREC Chair or delegate may decide to allow other persons access to HREC application files and site files. This decision may be taken at a HREC meeting or between meetings. The decision and reason for the decision to allow access to HREC files is to be recorded in the minutes at the next HREC meeting.

**41.5.** Note that Sponsor's representatives, or regulatory authorities should not be permitted to inspect the HREC files.

**41.6.** This monitoring, approved by the HREC Chair, may be extended to include random inspections of research sites, data, or consent documentation and interviews with research participants, or other forms of feedback from them.

**41.7.** The finish date for a research study refers to when no further contact with any data source is foreseen including the data analysis and reporting period.

**Reporting to the HREC**

**Progress reports**

**41.8.** Progress reports on all approved research should be submitted to the HREC annually, or more frequently if the level of risk is assessed by the HREC to warrant more frequent monitoring.

**41.9.** The Annual Report is due on the anniversary of the date on which ethics approval was given, since this is the only common date for multi-centre research. (or 30th April, annually, please refer to Reviewing HREC for instructions).

**41.10.** Progress reports should be in the format prescribed by the HREC and reporting templates should be available on their website.

**41.11.** Reports must be signed by the PI/CPI before submission.

**41.12.** A HREC may request that investigator-initiated studies are overseen by an independent safety committee, in which case the HREC will specify the reporting requirements in the approval documents.

**41.13.** Progress reports should be added to the agenda and reviewed by the HREC (unless delegated in the local HREC policies).

**41.14.** Where a progress report is not received by the due date, the HREC Administrator should send a reminder. If the report is still not received after a further period of one month, the HREC Chair should consider what further action should be taken. Where it is proposed to suspend the HREC's approval of the study, the matter should be considered at a meeting of the HREC.

**Safety monitoring and reporting - Responsibilities of the HREC**

**41.15.** The sponsor, through their independent safety monitoring arrangements, has the primary responsibility for monitoring the ongoing safety of the investigational medicinal product. The HREC should be satisfied that the sponsor's arrangements are sufficiently independent and commensurate with the risk, size and complexity of the trial.

**41.16.** The Reviewing HREC should:

b) Assess the safety of proposed trials, including whether the evaluation of the anticipated benefits and risks is satisfactory and ensure that the sponsor has proportionate systems in place to mitigate and manage any identified risks.
c) Satisfy itself that the sponsor's ongoing safety monitoring arrangements are adequate, including the justification for appointing/not appointing a Data Safety Monitoring Board and any 'stopping rules' or criteria for withdrawing individual participants from the trial.
d) Keep under review the adequacy and completeness of the informed consent process and documentation in the light of new information about risks and benefits.
e) Assess whether changes to the risk-benefit ratio that are reported by the sponsor are compatible with continued ethical approval.
f) Advise the TGA, investigators and their institutions of any decision to withdraw approval.
g) Keep under review the adequacy and completeness of the informed consent process and documentation in the light of new information about risks and benefits.

Note: While HRECs must keep approvals under review in light of safety information it receives, the responsibility for proactively monitoring the ongoing risk-benefit ratio of the trial remains with the sponsor at all times.

**41.17.** For more information on reporting of Adverse Events:

- NHMRC Safety monitoring and reporting in clinical trials involving therapeutic goods
- Risk-based management and monitoring of Clinical Trials involving therapeutic goods
- Reporting of Serious Breaches of Good Clinical Practice (GCP) or the Protocol for Trials Involving Therapeutic Goods
- NMA Monitoring and Reporting Framework.

**Reporting of urgent safety measures**

**41.18.** The CPI, or a PI at a trial site, may take appropriate urgent safety measures in order to protect the participants of a clinical trial against any immediate hazard to their health or safety.

**41.19.** The HREC, TGA and Investigators must be notified as soon as possible (and within 72 hours) and the Sponsor must be notified within 24 hours that such measures have been taken.

**41.20.** The notice should set out the reasons for the urgent safety measures and the plan for further action.

**41.21.** Notifications of urgent safety measures should be reviewed by the HREC Chair and then at the next meeting of the HREC. The HREC should consider whether the measures taken are appropriate in relation to the apparent risk to participants, and what further action the Sponsor or investigator(s) propose to take, for example the submission of amendments to the protocol. It is important to remember while HRECs must keep approvals under review in light of safety information it receives, the responsibility for proactively monitoring the ongoing risk-benefit ratio of the trial remains with the sponsor at all times NHMRC Safety monitoring and reporting in clinical trials involving therapeutic goods.

**41.22.** Where any concern arises about the safety or welfare of participants or the conduct of the research, the HREC should address these in writing with the PI/CPI.

**41.23.** The HRECs, RGOs and the institutions may develop clear guidance in accordance with the NHMRC Safety Monitoring and Reporting in Clinical Trials Involving Therapeutic Goods for investigators detailing the requirements for safety reporting and monitoring in clinical trials. This guidance should cover the requirements for both externally sponsored clinical trials and, if applicable, internally sponsored investigator/initiated or collaborative group sponsored clinical trials.

**41.24.** Sponsors should evaluate all safety information that is reported by investigators as well as safety information from other sources. It is recognised that a non-commercial Sponsor does not have access to all the safety data maintained by a commercial Sponsor, however, non-commercial Sponsors are responsible for evaluating all safety information available to them.

**41.25.** Sponsors of non-commercially sponsored trials are required to develop adequate safety review mechanisms, such as:

a) an independent, Data Safety Monitoring Board (DSMB),
b) a trial management committee,
c) liaison with a pharmacovigilance group (where there is commercial involvement in a study), or
d) other simpler but separate review processes, as agreed by the Reviewing HREC.

**Adverse events**

**41.26.** According to the NHMRC Safety Monitoring and Reporting in Clinical Trials Involving Therapeutic Goods, (Link) the Sponsor will provide the HREC with an annual safety report, Development Safety Update Reports (DSUR), Investigator's brochure updates and industry reports or Data Safety Monitoring Board (DSMB) reports. These reports should allow the HREC to assess whether ongoing safety monitoring is being conducted appropriately and that the trial's safety monitoring plans are being followed, and where necessary, are being adapted to take into account new findings as the trial progresses. These reports must also indicate where amendments to the protocol have been required due to safety issues.

**41.27.** The CPI/PI is required to provide a comment on the annual safety report, industry reports or DSMB collated reports.

**Serious Adverse Events (SAE) for drug and device clinical trials**

**41.28.** Sponsors should notify the TGA, HREC and investigators of all significant safety issues that adversely affect the safety of participants or materially impact on the continued ethical acceptability or conduct of a trial. Safety issues that meet the definition of an urgent safety measure should be notified within 72 hours, and all other significant safety issues should be notified within 15 calendar days of the Sponsor instigating or being made aware of the issue.

**41.29.** SAEs and USADEs are not reported directly to the HREC by the PI except in the following circumstances:
a) where there is sufficient concern for patient safety that an immediate protocol deviation or amendment is required, or
b) where the incident materially affects the ongoing ethics acceptability of the trial.

**41.30.** It is acceptable for the PI to notify the HREC using the same reporting template that is provided by the Sponsor.

**41.31.** Collations of SAEs occurring during the conduct of a clinical trial are provided by the Sponsor to the CPI/PI, in the form of annual reports.

**41.32.** Updated Investigator Brochures or Product Safety Information must be submitted to the HREC for consideration.

**41.33.** If any changes to the study are required, these must be submitted as an amendment.

**41.34.** All reports, including the cover letter/reporting template, should be uploaded in to ERM by the applicant.

**41.35.** Where individual institutions are not compliant with safety reporting to the Reviewing HREC, the Reviewing HREC has the ability to withdraw HREC Approval for that site.

**41.36.** Significant Safety Issues (SSIs) do not fall within the definition of a SUSAR and thus are not subject to the reporting requirements for SUSARs. SSIs usually require other action, such as the reporting of an urgent safety measure, an amendment, a temporary halt or an early termination of a trial. In addition, SSIs often result in safety-related changes to trial documentation. These amendments should be submitted to the HREC without undue delay.

**41.37.** The HREC is not required to approve Urgent Safety Measures but may consider whether any proposed actions are appropriate, such as the submission of an amendment relating to revised trial documentation.

**Tracking of medical devices**

**41.38.** Tracking of medical devices is undertaken as per TGA requirements and the Australian Regulatory Guidelines for Medical Devices (ARGMD).

**41.39.** For more information on the TGA guidelines refer to:

a) https://www.tga.gov.au/publication/note-guidance-good-clinical-practice
b) Australian clinical trial handbook

**41.40.** Device identifiers are placed into patient's medical notes and manufacturers are required to maintain a tracking system.

**Protocol violations and deviations**

**41.41.** The distinction between protocol violations and deviations is neither clearly understood nor consistently applied amongst Australian HRECs.

**41.42.** Protocol Violations, for the purposes of this document, are those variations to a protocol that implicate participant consent, participant safety or data integrity that compromises the ethical acceptability of the project.

**41.43.** Protocol Violations require retrospective notification to, and review by, an HREC.

**41.44.** Protocol Deviations, for the purposes of this document, relate to other matters and may not require notification to, or review by, a HREC but must be required to be recorded by the PI on a site file note (refer to local HREC requirements).

**41.45.** These definitions are consistent with ICH/GCP taxonomy.

**41.46.** The PI is responsible for reporting protocol violations to the HREC.

**41.47.** Violations should be noted at the next HREC meeting. unless delegated in the Terms of Reference (ToR).

**41.48.** The HREC should determine whether there is cause to consider if research misconduct has taken place. HRECs should refer to the NHMRC Guide to Managing and Investigating

Potential Breaches of the Australian Code for the Responsible Conduct of Research (2018) in making a determination.

**Reporting early termination of a study by the PI**

**41.49.** If advice is received via ERM or email from a member of the research team that the study is being terminated the study status on ERM should be updated to Terminated.

**41.50.** If the PI has not uploaded the study documentation in ERM, the documentation should be scanned and uploaded in the review documents tab of the study by the HREC Administrator.

**Suspension of HREC approval**

**41.51.** The HREC may suspend its ethics approval of a study if it is satisfied that circumstances have arisen such that a research project is not being, or cannot be, conducted in accordance with its ethics approval and that, as a result, the welfare and rights of participants are not, or will not, be protected.

**41.52.** Where the HREC considers it appropriate that the adverse event/s and/or monitoring report requires the immediate suspension or discontinuation of the ethics approval of the research project, the HREC should immediately notify the CPI (or PI for single site studies) and instruct them to:

a) Immediately cease all study related activities.
b) Ensure the health and wellbeing of participants is not compromised
c) Notify any study Sponsor of the HREC's decision.
d) Notify their RGO and the Department/HHS CE and
e) Notify PHA Administrator if PHA approval is in place.

If approval for the research is withdrawn by the HREC, the post approval status Withdrawn by HREC is given to the application.

**Final reports**

**41.53.** The HREC should receive notification from the CPI/PI that a study is finished. In this case, the HREC Administrator will mark the study on ERM as Finished.

**41.54.** A final report on all research given ethics approval should be submitted to the HREC within 30 business days of completion of the study, or on receipt of the Final Report from the Sponsor and should include a copy of the final published results.

**41.55.** Final reports should be added to the agenda and reviewed by the HREC unless delegated in the ToR. The study status should be updated in ERM to Closed and Archived.

**41.56.** It should be noted that notification from the PI to the HREC that the study is closed at the site does not constitute the final report unless so stipulated by the Sponsor. The final report is still required.

# 42. HREC 042: Archiving, storage and retention of HREC records and documentation

**General information for all HREC records**

**42.1.** All relevant retention disposal schedules have been approved by Queensland State Archives, for more information refer to:

- Health Sector (Clinical Records) Retention and Disposal Schedule
- Health Sector (Corporate Records) Retention and Disposal Schedule

**42.2.** The HREC should maintain a record of all research proposals received and reviewed, including at least the:

a) Name/s of the institution/s to which the research approval is provided.
b) Project identification number/s.
c) Name/s of principal researcher/s.
d) Title of the project.
e) Correspondence between the review body and the researcher about the review.
f) Acceptance or rejection of any changes to the proposal.
g) Proposed date of completion of the proposal.
h) Formal advice of final ethical approval or non-approval, with date.
i) Terms and conditions, if any, of approval of any proposal.
j) Duration of the approval.
k) Name of any other review body whose opinion was considered.
l) Mechanisms to be used to monitor the conduct of the research and
m) Relevance, if any, of the Commonwealth, State or Territory legislation or guidelines relating to privacy of personal or health information.

**42.3.** These records may be hard copies or in electronic format.

**Archiving completed studies**

**42.4.** Once a study has been completed and logged in ERM as being Completed and Archived, the project and all accompanying paper documentation may be removed from the HREC office and archived.

**42.5.** In addition, the HREC should retain on file a copy of each research proposal and application for ethical approval, including any information sheets, consent forms or relevant correspondence, in the form in which they were approved.

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

**42.7.** When archiving paper files, within each archive box, projects should be stored in numeric order according to the year they were approved.

**42.8.** If applicable a record of the archive box identifier is entered in ERM, under the Data tab page for the study, in the 'Notes' free text box.

# 43. HREC 043: Fees for HREC review of research applications

**General guidance**

**43.1.** The Australian Health Ethics Committee (AHEC) acknowledges the need for institutions to defray the costs of adequately resourcing a HREC, whilst outlining ethics issues and potential concerns associated with the charging of fees by institutions for the ethics review of a study. https://www.nhmrc.gov.au/about-us/leadership-and-governance/committees/australian-health-ethics-committee-ahec

**43.2.** AHEC recommends that organisations consider the following ethical issues prior to the implementation of fees:

a) The potential for the policy to compromise the integrity of ethics review of research applications.
b) The potential for loss of independence and autonomy of HRECs; and
c) The potential to prevent ethics consideration of research applications due to inability to pay, e.g., students.

**43.3.** Queensland, whilst acknowledging these concerns, has implemented a policy of charging fees for commercially sponsored and some non-commercial studies for:

a) HREC review.
b) Independent expert review and
c) Site specific assessments of research applications (unless exempt).

**Schedule of fees**

**43.4.** Review of new applications and substantial amendments by the HREC may be subject to a fee as per the locally published fee schedule.

**Payment of fees**

**43.5.** It is the responsibility of the researcher to provide the HREC/Finance Department with contact details of the Sponsor to whom the invoice will be sent.

**43.6.** Institutions may elect for invoices to be paid prior to dispatch of HREC approval letters.

**Exemptions from fees**

**43.7.** The HREC may elect to waive fees for non-commercial research as per local policy.

**What does the fee for ethics consideration by a Queensland Health HREC cover?**

**43.8.** The Queensland Health HREC fees enable HREC Administrators and members to fulfil their duties and support actives such as:

a) Funding and managing the HREC office, including costs for equipment, furniture, stationery to allow for compilation of agendas, secretariat duties for HREC meetings, e.g. minutes.
b) Liaising with other sites and reporting to AHEC, HHS Boards and the department as part of their Service Level Agreements.
c) Payments to external expert reviewers and others as necessary.
d) Advising and providing ethics education and training to researchers and HREC Administrators and members.
e) Maintaining ERM.
f) Liaising between the HREC and researchers regarding submissions, requests for clarification, responses, exempt and low risk review and incomplete applications.
g) Providing advice and assistance to researchers in the submission of research applications.
h) Liaising with other HREC Administrators regarding the status of submission of multi-centre research applications.
i) Training of HREC Administrators and members. This includes forwarding NHMRC announcements, notices of upcoming educational activities, arranging registration, travel and accommodation to conferences for HREC members.
j) Monitoring of approved research studies, requesting reports, locating and contacting non-compliant researchers, invitations to researchers to address the HREC.
k) Compliance with legislation and guidelines, keeping the HREC informed of the most recent developments surrounding topical issues.
l) Invoicing Sponsors for HREC fees, receipting, reconciliation, follow up of unpaid invoices and
m) Facilitating and participating in meetings of the HREC Administrators. This group consists of HREC Administrators from public and private hospital HRECs in Queensland. The group's focus is to disseminate information, provide assistance if requested in the establishment of HREC office systems, and to enhance the education and role of HREC Administrators with a view to formal training and accreditation, or meeting the costs of meetings and travel expenses of HREC members.

# 44. HREC 044: Handling research complaints and managing potential breaches of the 2018 Code

**General guidance**

**44.1.** The Guide to Managing and Investigating Potential Breaches of the Australian Code for the Responsible Conduct of Research (2018) sets out a model 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.

**44.2.** 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.

**44.3.** A Reviewing HREC's institution is required to manage concerns or complaints and investigate potential breaches of the 2018 Code.

**44.4.** Sites/HHSs must make public the process for receiving and resolving allegations of research misconduct. This should be consistent with the 2018 Code, the Guide to Managing and Investigating Potential Breaches of the Australian Code for the Responsible Conduct of Research, and the Queensland Health documents the Queensland Health documents Requirements for reporting suspected corrupt conduct E9 (QH-POL-218) and General Principles for Handling Research Complaints and Complaints Process for Research Misconduct. - General Principles for Handling Research Complaints and Complaints Process for Research Misconduct.

**Institutional responsibilities**

| | | |
|---|---|---|
| a) | Executive Officer (EO) | A senior officer in an institution who has financial responsibility for receiving reports of the outcomes of processes of assessment or investigation of potential or found breaches of the Australian Code and deciding on the course of action to be taken, which may include corrective actions, referral to an institution's disciplinary processes and/or other institutional processes. |
| b) | Designated Officer (DO) | A senior professional or academic institutional officer or officers appointed to receive complaints about the conduct of research or potential breaches of the Code and to oversee their management and investigation where required. |
| c) | Research Integrity Adviser (RIA) | A person with knowledge of the Australian Code and institutional processes nominated by the institution to promote the responsible conduct of research and provide advice to those with concerns or complaints about potential breaches of the Australian Code. |
| d) | Assessment Officer (AO) | A person appointed by an institution to conduct a preliminary assessment of a complaint about research. |

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

**44.6.** Any complaints received must also be forwarded to the HREC Administrator of the Reviewing HREC who will enter the complaint details on ERM, and to the local site RGO where the complaint applies, along with ORI if a PHA has been granted.

**44.7.** As per the 2018 Code and the Guide to Managing and Investigating Potential Breaches of the Australian Code for the Responsible Conduct of Research, the institutional CE will nominate advisers in research integrity to advise possible complainants about research conduct issues and explain the options open to persons considering making or having made an allegation.

**44.8.** Institutions should consider how preliminary assessments and investigations into potential breaches of the 2018 Code are to be conducted 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. 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.

**44.9.** 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.

**44.10.** The 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.

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

**44.12.** 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.

**44.13.** After a complaint is received, 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. The DO must assign the complaint to a suitable 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
e) Recommendations for further action.

**44.14.** 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.

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

**44.16.** If the DO determines an investigation is required, the following steps will be taken:

a) Prepare a clear statement of allegations.
b) Develop the terms of reference for the investigation.
c) nominate the investigation Panel (Panel) and Chair, when the Panel is more than one person and
d) Seek legal advice on matters of process where appropriate.

**44.17.** The Panel completes an investigation into the potential breach into the 2018 Code and compiles a comprehensive report that includes (amongst other things) the findings of fact that have been reached, a conclusion as to whether or not a breach of the 2018 Code occurred and whether or not the respondent is responsible for the breach, and its recommendations,

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

**Complaints concerning the HREC's review process**

**44.19.** The HREC Chair will notify the department/HHS CE of any complaints received, as soon as possible. Similarly, the department/HHS CE will inform the HREC Chair of any complaints received as soon as possible.

**44.20.** The HREC Chair will investigate the complaint and its validity and make a recommendation to the Reviewing HREC on the appropriate course of action.

**44.21.** If the complainant is not satisfied with the outcome of the HREC Chair's investigation, the complainant can refer to the institution's research complaints policy and request a further investigation of the complaint.

# Appendix 1: HREC Administrators checklist for all research projects

## Mandatory components including Lower Risk

| | Mandatory components for all submissions to a HREC, including Lower Risk |
|---|---|
| 1 | For all studies, a completed and signed HREA and supporting documentation. |
| 2 | Study Protocol. The HREA is not a study protocol. |
| 3 | CVs for CPI/PI (if applicable) |
| 4 | Form of Indemnity – HREC Review Only – must be provided with the HREA or commercially sponsored clinica<br>https://www.google.com/url?sa=t&rct=j&q=&esrc=s&source=web&cd=&ved=2ahUKEwiukMKrnOGDAxVvi68BH<br>content%2Fuploads%2Fsites%2F65%2F2020%2F11%2F1-October-2012-Medicines-Australia-HREC-ONLY-Form- |

# Appendix 2: Promotion of External Research in Queensland Health Newsletters and Communications

Title: Promoting Research: Guidance for Queensland Health

Dear Queensland Health Teams,

As part of our commitment to promoting valuable research we would like to provide you with guidelines regarding the promotion of external research in Queensland Health newsletters and communications i.e. QHEPS. It is crucial to ensure that the research we endorse aligns with our mission and does not impose an undue burden on our staff.

Research that does not require Queensland Health Human Research Ethics Committee (HREC)/National Mutual Acceptance (NMA) approvals or governance authorisation:

There may be instances where you are asked to promote external research, such as surveys conducted at universities, that does not require Queensland Health HREC or governance authorisations*. In such cases, the following considerations should be taken into account before promoting the research:

1. Relevance and Worthy Contribution: Evaluate the research to determine its relevance to healthcare, public health, or related fields. Assess whether it provides valuable insights, knowledge, or potential benefits to our staff or the wider community. Seek advice from your Executive Director.

2. Relevant approvals: Confirm it has relevant ethics approvals and the researcher's institutional governance authorisation and include those reference numbers with any promotional material.

3. Time Commitment: Recognise that promoting external research may inadvertently require some staff time and resources. Weigh the potential impact on the productivity and workload of Queensland Health employees before endorsing such initiatives.

4. Non-Collaborative Research: Clarify that the research being promoted is not a collaborative effort involving Queensland Health staff, data or resources (that would require Queensland Health HREC/NMA approval and governance authorisation). Seek advice from your local research office. If any staff members express interest in participating, emphasise that they should engage in the research on their own time and not during working hours.

By adhering to this guidance, we can effectively support research that is worthy, aligns with our mission, and minimises the impact on our dedicated staff. As an organisation committed to promoting evidence-based practices, it is crucial that we carefully evaluate and endorse research initiatives that contribute to the development of healthcare in Queensland.

* A scenario to illustrate this: James Cook University (JCU) may be researching differences in exercise habits between office workers in Townsville and those in outlying areas. The primary goal is to compare exercise routines between individuals in Townsville city and rural areas, rather than contrasting Queensland Health office workers with any specific group.

To ensure correct authorisation, you must confirm the relevant ethics and institutional approvals before promoting this research. It is advisable to inquire about JCU's ethics approval and governance authorisation for this project since it is a JCU researcher. This will inform you about the necessary steps for promotion. If the research were to involve Queensland Health and make distinctions or comparisons concerning their workforce, Queensland Health's specific research ethics approval and governance authorisation would be required. This guide aims to provide a clear delineation of different approval requirements.