

Health and Medical Research, Preventive Health Unit

Standard Operating Procedures for Queensland Health HREC Administrators

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Acknowledgements

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Introduction

Purpose and scope

Use of these SOPs ensures compliance to nationally accepted guidelines for ethical review. These procedures are to be used in conjunction with the *National Health and Medical Research Council's (NHMRC) National Statement on Ethical Conduct in Human Research (2007) (The National Statement)*, the *NHMRC and Universities Australia Australian Code for the Responsible Conduct of Research (2007) (The Code)* and the Queensland Department of Health (DoH) *Research Management Policy (2012) and Directive 2013*.

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

Implementation

HRECs may develop additional local operating procedures to deal with local matters not addressed in these SOPs. Local SOPs should be made publicly available on the institution's website.

HRECs will direct researchers to submit research applications using either the National Ethics Application Form (NEAF) or the Queensland DoH Low and Negligible Risk Research (LNR) form. There are two NEAF templates, the NHMRC version accessed at www.neaf.gov.au or the Online Forms NEAF accessed via <http://www.ethicsform.org>. Both versions of the NEAF are acceptable as they ask the same questions but are supported by different IT platforms. However, the NHMRC version must be transferred into the Online Forms version to enable processing by the HREC.

A Queensland Health HREC will request researchers to upload all supporting documentation onto the Online Forms version of the application form.

For multi-centre research studies, an HREC that has been assessed and certified under the National Certification Scheme is the single HREC body to conduct the ethical and scientific review a multi-centre research study. No other HREC will be involved in the ethical review of an application which is being or has been reviewed by a certified HREC under the State-wide Single Ethical Review Process (SERP), or, in the case of clinical trials, the National Mutual Acceptance model..

HRECs should ensure that the HREC has access to the expertise necessary to enable it to address scientific and ethical issues. This may necessitate consulting outside the HREC membership.

Definitions and Abbreviations

Adverse event (AE)	<p>Any untoward medical occurrence in a research participant using an investigational product which does not necessarily have a causal relationship with the product.</p> <p>Therefore, an adverse event (AE) can be any unfavourable and unintended sign (including an abnormal laboratory finding), symptom, or disease temporally associated with the use of a medicinal (investigational) product, whether or not related to the medicinal (investigational) product.</p>
Amendment	<p>A change to the Human Research Ethics Committee (HREC) approved application including the protocol or supporting documentation. If the amendment is administrative in nature an HREC amendment review fee may be waived for commercially sponsored research.</p> <p>Examples of Administrative Amendments include:</p> <ul style="list-style-type: none"> • correction of typographical errors in any study documentation; • amended contact details for the sponsor or study staff, and • appointment of new support staff.
Applicant	<p>For multi-centre studies the Coordinating Principal Investigator (CPI). For single site studies the Site Principal Investigator (PI).</p>
Associate Investigator (AI)	<p>Another term used for Sub-investigator</p>
<i>AU RED</i>	<p>Australian Research Ethics Database. A secure web-based research ethics database used by HREC Administrators, Research Governance Officers (RGOs) and other ethics office administrative staff to store ethics documents, applications and correspondence in relation to studies submitted to a Queensland Health Ethics Committee</p>
The Australian Code for the Responsible conduct of Research (The Code)	<p>The <i>Australian Code of for the Responsible Conduct of Research (2007) (The Code)</i>. This guides institutions and researchers in responsible research practices and promotes integrity in research. It shows how to manage breaches of The Code and allegations of research misconduct, how to manage research data and materials, how to publish and disseminate research findings, including proper attribution of authorship, how to conduct effective peer review and how to manage conflicts of interest. It also explains the responsibilities and rights of researchers if they witness research misconduct.</p>
Central Coordinating Service (CCS)	<p>The Central Coordinating Service (CCS) allocates multi-centre studies to an appropriately Certified HREC for review. This will be displayed on <i>AU RED</i> as <i>Applications Booked in through CAS</i>.</p> <p>Researchers must complete a booking form to enable the study to be allocated for HREC review. The booking form can be found by following this link: http://www.health.qld.gov.au/ohmr/html/regu/cen_coord_serv.asp</p> <p>All studies being conducted in more than one site must be referred to the CCS.</p>
Certified HREC	<p>An HREC which has had its processes assessed and certified under the National Health and Medical Research Council (NHMRC) National Certification Scheme. NHMRC certification lasts for three years.</p> <ul style="list-style-type: none"> • To access information on the NHMRC Certification Scheme, click on this link: http://hrep.nhmrc.gov.au/ • To find a certified HREC, follow this link:

	http://www.nhmrc.gov.au/files/nhmrc/file/health_ethics/homer/Certified%20ethical%20review%20process%20v0_11.pdf
Clinical Audit	<p>Quality Assurance programmes may use planned clinical audits along with other monitoring tools to assure that standards are being met. A Clinical Audit is not research.</p> <ul style="list-style-type: none"> •Clinical audit tells us whether we are doing what we should be doing and how well we are doing it. Clinical audit is about quality and finding out if best practice is being practised. •Research is about obtaining new knowledge and finding out what treatments are the most effective. Research tells us what we should be doing. <p>Health and Medical Research policy is to make a clear distinction between clinical audit and research and the policy is that clinical audit does not need approval from a research ethics committee. Even if an ethical opinion is sought for a clinical audit and even if an application is made under the Public Health Act to disclose confidential information without consent, clinical audits do not require research authorisation as they are not research activities. Local approval processes apply for quality assurance activities.</p>
Clinical Research Coordinator (CRC)	The person designated by the Principal Investigator (PI) to be responsible for coordinating the conduct of the research project, including scheduling of participant visits, liaison with Sponsor management personnel and the HREC / Research Governance Office(r) (RGO). May also be known as the Site Coordinator or Contact Person.
Contact Person	The person designated by the Principal Investigator (PI) to be responsible for liaising with the HREC / Research Governance Office(r) (RGO). May also be known as the Site Coordinator or Clinical Research Coordinator.
Clinical Research Associate (CRA)	A Sponsor or Contract Research Organisation (CRO) representative employed to monitor clinical trials. The CRA ensures compliance with the clinical trial protocol, checks site activities, reviews Case Report Forms (CRFs) and acts as a communication conduit between sites and the sponsor organisation.
Confidential Information	<p>confidential information means any information that—</p> <p>(a) is about a person who is receiving or has received a public sector health service; and</p> <p>(b) could identify the person.</p> <p><i>Hospital and Health Boards Act (2011)</i></p> <p>See also <i>Personal Information</i></p>
Contract Research Organisation (CRO)	An organisation (commercial, academic or other) contracted by the sponsor to perform one or more or a sponsor's trial-related duties or functions.
Coordinating Principal Investigator (CPI)	<p>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.</p> <p>The CPI and their team are responsible for coordinating the HREC applications and correspondence throughout a multi-centre study, on behalf of the Accepting PIs for which the CPI is responsible.</p> <p>For single site studies the terms Coordinating Principal Investigator, Coordinating Principal Researcher, Site Principal Investigator and Principal Investigator are all</p>

	<p>synonymous.</p> <p>Guidance documents for undertaking the role of a CPI are on the HMR website: http://www.health.qld.gov.au/ohmr/html/Health Research Team/for_researcher.asp</p>
Department of Health (DoH)	The Department of Health manages the health system in Queensland
DoRA	A Queensland Department of Health website listing all research studies being conducted within Queensland Health. Permission must be obtained from the Sponsor to publish details to the website. The consent to publish in DoRA is a question in the Site Specific Assessment form (SSA).
Good Clinical Practice (GCP)	An international ethical and scientific quality standard for designing, conducting, recording and reporting trials that involve the participation of human subjects. May also be referred to as ICH GCP (International Conference on Harmonisation). http://ichgcp.net/
Health and Medical Research (HMR)	Health and Medical Research formally known as the Research Ethics & Governance Unit (REGU) or the Office of Health and Medical Research.
<i>Hospital and Health Boards Act 2011</i>	The Act that recognises and give effect to the principles and objectives of the national health system agreed by Commonwealth, State and Territory governments. The object of the Act is to establish a public sector health system that delivers high quality hospital and other health services in Queensland having regard to the principles and objectives of the national health system. Part 7 of the Act provides the legislation that governs release of Confidential Information. http://www.legislation.qld.gov.au/LEGISLTN/CURRENT/H/HHNA11.pdf
Hospital and Health Service (HHS)	Hospital and Health Services (HHSs) operate and manage a network of public hospitals and health services within a defined geographic or functional area within Queensland.
Human Research Ethics Committee. (HREC)	Human Research Ethics Committees (HRECs) review research proposals that involve humans or their tissue or data research involves humans. HRECs are established by organisations, which register their HREC with the NHMRC. It may also be referred to as the Reviewing HREC in multi-centre research studies.
HREC Administrator	An employee of the institution who provides administrative support and advice on the institution's processes for ethical review of research studies. The HREC Administrator reports to the Chair of the HREC in matters related to the activities of the Committee. The terms HREC Coordinator and HREC Administrator are interchangeable.
Individually Identifiable Data	Where the identity of a specific individual can reasonably be ascertained. Examples of identifiers include the individual's name, image, date of birth, or address (<i>National Statement on Ethical Conduct in Human Research, 2007</i>)
Low and Negligible Risk Research Form (LNR Form)	An application form used for research which is defined as low or negligible risk. The form is available on the <i>Online Forms</i> website.
Low Risk	Section 2.1.6 of <i>The National Statement (2007)</i> describes research as low risk where

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

	<i>Public Health Act 2005 (PHA)</i> approval is required.
Personal information	<p>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.</p> <p><i>Information Privacy Act 2009</i></p> <p>See also <i>Confidential Information</i></p>
Principal Investigator (PI)	<p>The investigator responsible for the overall conduct of the research study at an individual site.</p> <ul style="list-style-type: none"> • For multi-centre studies the PI may be known as the Accepting PI if they do not have CPI responsibilities. • For single site studies the terms Coordinating Principal Investigator, Coordinating Principal Researcher, Site Principal Investigator and Principal Investigator are used interchangeably.
Quality Assurance Activity (QA)	<p>A clinical governance activity that is a requirement of the compulsory <i>National Safety and Quality Health Service Standards and an associated Australian Health Service and Quality Accreditation (AHSSQA)</i> Scheme.</p> <p>http://www.safetyandquality.gov.au/wp-content/uploads/2011/09/NSQHS-Standards-Sept-2012.pdf</p> <p>This includes patient satisfaction surveys, surveillance and monitoring and clinical audits. If there are research elements then it will be reviewed under the research review process.</p>
Queensland Health	The term used to describe reference to the Department of Health and Hospital and Health Services.
Re-identifiable Data	Data from which identifiers have been removed and replaced by a code, but it remains possible to re-identify a specific individual by, for example, using the code or linking different data sets (<i>National Statement on Ethical Conduct in Human Research, 2007</i>)
Research Authorisation	Authorisation issued by the HHS Chief Executive (CE) or delegate to conduct research at a Site within their jurisdiction. Authorisation is contingent upon receiving HREC approval and completion of governance requirements which may include an SSA form. The maximum time given for Research Authorisation is 25 days from receipt of a valid governance application.
Research Governance Office(r) (RGO)	<p>The Office(r) or coordinated function within an institution / HHS whose responsibilities are:</p> <ul style="list-style-type: none"> • assessing the site-specific aspects of research applications; • making recommendations to the HHS CE or delegate as to whether a research study should be granted authorisation at that site; and • monitoring authorised research at the site to ensure it meets appropriate standards (research governance).
Research Governance Process	The process by which an RGO assesses the suitability of study to take place within their HHS and recommends authorisation by the HHS CE. Once authorised, the study may commence at that HHS.
Reviewing HREC	The certified HREC that has been allocated to review multi-centre research studies

60-day clock	The period of 60 review days allowed for the deliberation of an ethical decision on an application. For research not requiring review at a full HREC meeting, the clock starts on receipt of a valid application. For research requiring review at a full HREC meeting the clock starts on the relevant HREC meeting closing date. The 60-day time limit excludes stop clock days. May also be called 60 Review Days.
Serious Adverse Event (SAE)	The definition of a Serious Adverse Event (SAE) will be defined by the Sponsor and included in the Protocol. Generally, an SAE in human drug trials is defined as any untoward medical occurrence that at any dose, results in death, is life-threatening, requires inpatient hospitalization or prolongation of existing hospitalization, results in persistent or significant disability/incapacity, is a congenital anomaly/birth defect, or requires intervention to prevent permanent impairment or damage. Suspected Unexpected Serious Adverse Reactions (SUSARs) are considered a subset of SAEs.
Single Ethical Review Process (SERP)	The mechanism to allow ethical review of multi-centre research by one NHMRC Certified HREC rather than submitting a study to multiple HRECs for review.
Single site research	Research to be conducted at one site only.
Site Coordinator	The person designated by the Principal Investigator (PI) to be responsible for liaising with the HREC / RGO. May also be known as the Clinical Research Coordinator, Contact Person or Study Liaison Officer.
Site-Specific Governance Amendment	An amendment request for an authorised research study that may be submitted by the applicant to the RGO only (thereby by-passing the HREC). Examples would be changes to site contracts and changes to participating site staff other than the PI.
Site Specific Assessment (SSA) Form	A tool to assist RGOs in the research governance process to document the level of support and suitability of a research study to be conducted at a site, irrespective of whether that study is multi-centre or single site.
Site Start Date	The site start date refers to either the anticipated first point of recruitment (i.e. the date when the advertising or screening for participants begins) or start of data collection.
State Specific Modules	Victoria, Western Australia and the Australian Capital Territory have developed additional modules for HREC review that must be completed and submitted as part of the HREC review of clinical trials, when sites from those States / Territories are participating in multi-centre research. For further information go to: Vic: http://www.health.vic.gov.au/clinicaltrials/application-instructions.htm#vsm WA: http://www.health.wa.gov.au/researchdevelopment/home/hrec.cfm#ethics ACT: http://healthresearch.anu.edu.au/human-research-ethics-committee.html
Stop Clock facility	For HREC applications, the time when the 60-day clock is stopped while awaiting a satisfactory response from the applicant to a written request from the HREC for further information or clarification. The clock will re-start automatically when a response from the applicant is logged in to <i>AU RED</i> . For SSA applications, the time when the 25-day clock is stopped while awaiting a satisfactory response from the applicant to a written request from the RGO for further information or clarification.
Study Site	Means the location(s) under the control of the Institution where the study is actually conducted.

Study Start Date	The study start date refers to either the anticipated first point of recruitment (i.e. the date when the advertising or screening for participants begins) or the start of data collection at any site involved in the study
Sub Investigator	May also be called Associate Investigator (AI) or Associate Researcher. ICH GCP defines a sub-investigator as “any individual member of the clinical trial team designated and supervised by the investigator at a trial site to perform critical trial-related procedures and/or to make important trial related decisions”.
25-day clock	The period of 25 days allowed for the SSA authorisation by the HHS CE or delegate of a research application. The clock starts on receipt of a valid SSA.
Therapeutic Goods Administration (TGA)	The Therapeutic Goods Administration is the agency responsible for regulating therapeutic goods: Follow this link for further information: http://www.tga.gov.au/about/about.htm
Validation	An administrative check carried out by an HREC Administrator or RGO to verify that all applicable application documentation is submitted prior to review. Decisions on validation should be made within one week of receipt.
Validation date	<ul style="list-style-type: none"> • For research not requiring review at a full HREC meeting, the date on which a valid application is received by an HREC Administrator. • For research requiring review at a full HREC meeting, the relevant HREC meeting closing date. • For research governance: the date on which a valid application is received by a RGO.

SECTION 1: New Applications for Ethical Review

Receipt of Research Applications

All Studies



- 1.1. All new applications for ethical review are to be submitted using the *Online Forms* version of the National Ethics Application Form (NEAF) or the Low and Negligible Risk Form (LNR) accessed via

<http://www.ethicsform.org> (Note the NHMRC NEAF must be converted to the *Online Forms* application version to enable uploading to *AU RED*).

- 1.2. Applications intended for review at the next HREC meeting must be delivered to the HREC Administrator by 12:00 midday on the closing day for applications. Late submissions will be held over until the following HREC meeting unless the investigator has negotiated the late submission with the HREC Administrator.
- 1.3. All applications must be registered on *AU RED* i.e. given an HREC number, within two business days of being delivered to the HREC office. Processing of the application may occur later.
- 1.4. Applications will be submitted directly by the CPI, PI or delegate to the HREC.
- 1.5. Upon receipt of an application, the HREC Administrator must check the following:
 - the application has a submission code;
 - all required signatures are in the application;
 - signature pages have the same submission code as the remainder of the document, or there is an accompanying explanation as to why the submission codes are different, and what amendments were made to the application form; and
 - all supporting documentation has been electronically attached to the application by the researcher.
- 1.6. If the application and supporting documentation have not been uploaded via the *Online Forms* website, the HREC administrator should request that the researcher uploads the application and supporting documentation. This ensures that all data can be efficiently uploaded into *AU RED*.
- 1.7. The administrator must check all submitted documentation has correct version details and descriptors when registered on *AU RED*, so that the approval documentation will be correct and complete. Where inconsistencies are found, the administrator should contact the researcher to notify them that the application will be deemed invalid until corrected.
- 1.8. Applications must be accompanied by a cover letter and completed HREC Submission Checklist for Researchers, and must contain the required number of copies of all documents as specified by the individual HREC. (Number of copies required will vary according to number of HREC members and local HREC review policy).
- 1.9. A list of meeting dates will be made available by the HREC office to prospective researchers and HMR, by 31 October of the preceding year.
- 1.10. Photocopying and collating the required number of copies of documents is the responsibility of the applicant and not the HREC. If bundles are submitted uncollated, they will be deemed to be invalid until collated by the researcher.
- 1.11. Every application should contain a study synopsis or protocol. The application form is NOT the protocol.

Multi-centre Studies

- 1.12. All studies will have a Coordinating Principal Investigator (CPI).
- 1.13. Submission of a multi-centre research project, for review by a Certified HREC, will be made via the Queensland Department of Health Central Coordinating Service (CCS) booking form.

- 1.14. The HREC Administrator will receive an automatically generated notification from the CCS on *AU RED*.
- 1.15. The HREC may communicate with the CPI or nominated Study Coordinator or contact person.
- 1.16. If a multi-centre application is delivered directly to the HREC Administrator without being allocated via the CCS, the HREC Administrator can choose to accept the application, and notify CCS of the HREC number that has been allocated to the application, or require the applicant to contact CCS for allocation of the application

Student Research

- 1.17. All students undertaking research in Queensland public health institutions require a supervisor. If the student's primary supervisor is not a Queensland Health employee, the student should nominate an educational supervisor or Student Liaison Officer from Queensland Health.

Inclusion of Private Sites in an HREC Review

- 1.18. Sites to be covered by this HREC review must be listed in the application. If there are private institutions listed, the following points must be considered:
 - does the private institution have its own HREC and has it reviewed this project?;
 - will the private institution accept the review of a Queensland DoH and HHS HREC?;
 - 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?;
 - if commercially sponsored research, has the private institution been listed on the Form of Indemnity – HREC Review Only?; and
 - if investigator initiated research, has the private institution offered indemnity to the Queensland HHS and HREC?

National Mutual Acceptance (NMA) of Ethical and Scientific Review of Multi-Centre Clinical Trials in Public Health Organisations

- 1.19. Only one HREC review is required for eligible multi-centre clinical trials being undertaken in Public Health Organisations in participating states. Multi-centre clinical trials may be scientifically and ethically reviewed by any one of the Certified HRECs in those jurisdictions participating in the NMA model. Researchers can choose the State to which they wish to submit.
- 1.20. Where there is a site located in Victoria, Western Australia or the Australian Capital Territory (once they have signed the Agreement) the specific Module for that State or Territory must be completed (preferably by a researcher from the relevant State / Territory, as nominated by the Sponsor of the trial), and submitted by the CPI, along with the Application Form and all other supporting documentation, to the Reviewing HREC.
- 1.21. The HREC approval will apply to all participating sites, as identified in the CPI's cover letter.

Conducting the HREC Review under National Mutual Acceptance

- 1.22. Studies allocated to an HREC for review under the NMA are processed as for any multi-centre study.
- 1.23. All participating sites for which the HREC review is valid must be listed on the HREC Approval letter.
- 1.24. For a list of participating organisations, please refer to the NMA *Participating Organisations* document at this website: http://www.health.qld.gov.au/ohmr/html/regu/mutual_accept.asp

Clinical trials not included in National Mutual Acceptance

- 1.25. Some studies are excluded from NMA because of State specific requirements. The following clinical trials are currently excluded from NMA:
 - Clinical trials involving persons in custody or staff of the jurisdictional Justice Health departments;
 - Clinical trials specifically affecting the health and wellbeing of Aboriginal and Torres Strait Islander people and communities;
 - Clinical trials requiring access to state-wide data collections; and
 - Clinical trials involving access to coronial material.
- 1.26. The above 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.

MOU for Mutual Acceptance of Ethical and Scientific Review of Multi-Centre Research Studies in Queensland Health and Mater Health Services (MHS) Brisbane

- 1.27. Only one HREC review is required for multi-centre research studies being undertaken in Queensland Health and MHS.
- 1.28. All multi-centre studies must be allocated to a Reviewing HREC via the CCS.
- 1.29. The HREC review from the MHS HREC is accepted throughout Queensland Health for all types of research, and is not restricted to clinical trials.
- 1.30. The MHS HREC is not a signatory to the Interstate MOU, therefore the review of the MHS HREC will not be accepted in public institutions outside of Queensland.
- 1.31. The MHS is unable to participate in NMA.

Accepting the HREC Review for Studies not included in the National Mutual Acceptance model, or from a Non Certified Committee

- 1.32. If a research project has been reviewed and approved by an HREC 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 HREC at their institution only.

- 1.33. Section 5.3 of the *National Statement* endorses minimisation of duplication of HREC review.
- 1.34. The researcher should discuss with the HREC Chair via the HREC Administrator, the possibility of acceptance of the original HREC review. All documentation provided to the original HREC must be supplied to the HREC Chair for consideration.
- 1.35. The HREC Chair will review the application, bearing in mind any local circumstances relevant to the project.
- 1.36. If the HREC Chair accepts the project and study documentation without need for amendment, the study can be accepted, and this decision will be tabled at the next HREC meeting. The HREC Administrator will issue an HREC Approval Letter prior to the full HREC meeting. Research governance processes must be undertaken in the normal manner.
- 1.37. If the HREC Chair decides that amendments to the submitted protocol or study documentation are required, the project may be referred for full HREC review. This does not apply to Administrative Amendments.
- 1.38. This process is only applicable to single site studies. If the project that has been reviewed by the original HREC is multi-centre within the State, it must be submitted for HREC review via the CCS to a Certified HREC.
- 1.39. All reporting to the HREC is made to the Local HREC.

Uploading Applications to *AU RED*

All Studies

- 1.40. All studies must be registered on *AU RED* within two business days of the documentation being delivered to the HREC office. Registration of the study allocates the unique identifying number - HREC number - for the project.
- 1.41. Ongoing processing of the application – for validation and allocation to a meeting - may occur immediately, or may be delayed until a more appropriate time. However, validation of study must occur within seven days of receipt of the application.
- 1.42. NEAF applications created on the NHMRC version of the NEAF can be reviewed by the HREC, but must be converted by the researcher to an *Online Forms* version of the NEAF (accessed via <http://www.ethicsform.org>), to enable uploading into *AU RED* and creation of the Site Specific Assessment (SSA) forms. Refer the researcher to the Researcher User Guide or the *Online Forms* Help Desk for guidance on converting the NHMRC NEAF to the *Online Forms* version.
- 1.43. To upload an Online Forms application, please refer to the *AU RED* user Manual, accessed via the *Help* tab in *AU RED*.
- 1.44. If there is no submission code on the application it is still in draft format and will be considered invalid. The HREC Administrator must contact the researcher and ask them to create a submission code for their application and inform the HREC Administrator of the submission code to enable uploading into *AU RED*. The HREC Administrator can decide whether to request new copies of the application with the submission code on each page (and new signature pages) or accept a statement from the PI or CPI that no changes have been made to the application form between submitting it and later obtaining a submission code.

- 1.45. The HREC administrator must ensure that all documents for review by the HREC have been uploaded by the researcher and are listed in the checklist on *AU RED*. This ensures that the HREC Administrator receives and has a record of all supporting documentation. Names, dates and version numbers of uploaded documents from this list, will also be automatically populated into the HREC approval letter.

Multi-centre Studies

- 1.46. When a multi site study has been allocated to a Reviewing HREC via the CCS, an automatically generated email is sent to the HREC Administrator of the Reviewing HREC (copied to the applicant and CPI). Applications that have been allocated for review by your HREC via the CCS will appear under the Work Area alert: Applications booked in through CAS.
- 1.47. Under this alert is a list of all HREC applications that have been booked in through the CCS. The alert is cleared when the study has been recorded as either valid or invalid on the *Application - Validate/Start* page.
- 1.48. To process the application, follow the guidance in the *Help* tab in *AU RED*. Complete the relevant details, upload the *Online Forms* application, check the uploaded supporting documentation and notify the researcher of any documents which have not been uploaded. When all appropriate documentation is uploaded, the study can be validated.
- 1.49. Once the application has been validated, it can be assigned to a meeting from the *Application - Meetings* page. For guidance on this process, view the *AU RED* User Manual in the *AU RED Help* tab.
- 1.50. If the study is being reviewed under the NMA model, the *Mode of HREC Review* field on the *Details* tab must be changed to *National (NHMRC)*.
- 1.51. If the study is being reviewed for Queensland only, the *Mode of HREC Review* field on the *Details* tab must be changed to *State*.
- 1.52. Multi-centre Low and Negligible Risk Studies must also be allocated to a Reviewing HREC via CCS.

Uploading Supporting Documents

- 1.53. If the applicant has uploaded their supporting documentation to their *Online Forms* application, these documents will automatically be uploaded when the HREC Administrator imports the *Online Forms* application by entering the submission code into *AU RED*.
- 1.54. If the applicant uploads a new document or a newer version of a supporting document to their *Online Forms* application, they should notify the HREC Administrator that the revised version is available. The revised version can then be uploaded to the *Application - Checklist* page simply by re-entering the submission code on the *Details* page (by clicking on the *Upload Online Form Data* button. Click *Continue* but do not re-upload the contacts by skipping to the *Checklist* tab). *AU RED* will keep a copy of all document versions uploaded.

Validation of Applications

- 1.55. An application is accepted as valid if it meets all the following criteria:

- the HREC’s checklist has been completed and submitted;
 - all documents relevant to the particular application listed in the checklist have been submitted and electronically uploaded to the application;
 - the application has been signed by the CPI and has a submission code, and
 - all documentation has been collated into bundles with each bundle containing a copy of all required paperwork.
- 1.56. Regarding the signatures of the Investigators, only the signature of the CPI is required on the NEAF, unless the applicant is a student, in which case, the signature of the Student Supervisor is also required. Individual PIs will sign the SSA Forms.
- 1.57. The Head of Department is not required to sign the NEAF as they will sign the SSA.
- 1.58. The applications may be signed electronically via the *Online Forms* site by the CPI (multi-centre applications) or PI (single site applications). Applications with original signatures can be submitted. HREC Administrators should also accept faxed or scanned signed applications. All hard copy signatures should be scanned and uploaded into *AU RED*.
- 1.59. Some documents must have original signatures e.g. the CTN Form and Forms of Indemnity. However, for the *Online Forms* application, signature pages must have the same submission code as the remainder of the document. If not, the HREC Administrator should request a written explanation from the researcher as to what changes were made to the application, and request an acknowledgement from the CPI and any other signatories that they are aware of the changes.
- 1.60. In some cases, an e-mail from the CPI/PI or student supervisor may be accepted in place of a “wet ink signature”. This is acceptable where the researcher is able to demonstrate the supervisor’s intent to support the project.

Invalid Applications

- 1.61. An application is invalid if:
- major discrepancies are present e.g. the submission is not on the appropriate application form (NEAF or LNR form) or is incomplete;
 - the required supporting documentation (such as protocol, information sheet & consent form, questionnaires and other tools) is not electronically uploaded and submitted with the application;
 - the documentation is not signed by all relevant parties;
 - signature pages have a different submission code from the remainder of the application without an accompanying explanation from the researcher
 - the application is so poorly written, that it is deemed by the HREC Chair to be invalid and cannot be reviewed by the HREC until it has been re-written, undergone peer review and been re-submitted
 - submitted documents have not been collated into bundles with one copy of each document in each bundle (as advised on the HREC checklist)
- 1.62. Applications marked as *Invalid* do not require a new HREC number when re-submitted.

Processing of Applications

- 1.63. It should be encouraged that applications for HREC review may be submitted on any day, not just the closing date so as to decrease workflow pressures on closing day.
- 1.64. Upon receipt of the application, if possible the HREC Administrator should check that the application is complete. The researcher should be asked to wait in the HREC office whilst this check is undertaken so that any remedial actions can be communicated directly to the researcher.
- 1.65. The decision whether or not an application is complete can be made by the HREC Administrator, although if in doubt the Chair should be consulted.
- 1.66. For incomplete or invalid applications the CPI and study contact person will be notified by the HREC Administrator that:
 - the application will not be accepted for the next meeting and that the application will require further attention prior to HREC review (the researcher should be given guidance on remedial action); or
 - the CPI must supply further information in relation to the application, by a specific date or time for the application to be reviewed at the upcoming meeting.
- 1.67. For applications requiring full HREC review the validation date is the closing date for submissions.
- 1.68. For applications not requiring full ethical review e.g. single site low and negligible risk projects, the date of receipt of the application in the reviewing office is marked on the application. The validation date has the same terms as outlined above. If all documentation and signatures are in place when the application is received in the reviewing office, then the date of receipt and the validation date are the same. However, if the application is invalid, the date of receipt will be different from the validation date.
- 1.69. A letter / email acknowledging receipt of the application, and notifying the applicant if the application is *Valid* and able to be reviewed or *Invalid* and requires amendment and / or additional documentation may be sent by the HREC Administrator within one week of receipt, via the following letters (SL1 & SL2). The acknowledgement letter /email includes the (HREC number) allocated to the application.

Allocation of Applications for Ethical Review

- 1.70. All applications must be received by the HREC Administrator by 12:00 midday on Closing Day.
- 1.71. Where possible, applications will be forwarded by the HREC Administrator to the reviewer/s at least 10 days prior to the meeting of the scientific sub-committee (if applicable), or at least 10 days prior to the meeting at which the application will be reviewed by the committee.
- 1.72. The period of 60 calendar days (minus clock stops), within which an ethical decision must be given, begins on:
 - the closing date for submissions, for applications requiring full HREC review; or
 - when a valid application is received by the reviewing body, for applications not requiring full HREC review.

Revision of Applications following Submission

- 1.73. Once an application has been validated, the researcher will be unable to make any revisions prior to the review by the scientific sub-committee, external expert reviewers or HREC.
- 1.74. If the applicant considers it necessary to revise the application form or the supporting documentation prior to review by the HREC, he/she should withdraw the application and resubmit it at a later date.
- 1.75. 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 ethical decision has been given, a single copy of the corrected document should be submitted. These may be included in the applicant's response to a request made by the HREC for further information or clarification.
- 1.76. The changes should be clearly highlighted in the updated documents using Microsoft Word™ Track Changes function or similar, and the relevant documents given new version numbers and dates and must be accompanied by a cover letter explaining clearly what the changes are and why these have been made.
- 1.77. 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. These updated documents should be recorded on *AU RED*.
- 1.78. If the Chair considers the proposed revisions to be significant and unrelated to the matters raised by the HREC in the ethical review, the applicant may be advised to withdraw the application and re-submit it. Alternatively, the revisions may be submitted to the Committee at the next meeting.
- 1.79. For revisions made after a final ethical decision has been given, refer to the procedures for review of amendments in Section 4.

Registry Studies

Setting up a Registry

- 1.80. Applications for Registry Studies are frequently submitted for HREC review.
- 1.81. 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 low risk and could be reviewed via the LNR process. However, a registry that lists patients with a particular disease may be considered as more than low risk and may need to be reviewed by the full HREC, using a NEAF Application.
- 1.82. If the registry is multi-centre, it may be reviewed by the LNR process provided that the LNR process was in place and reviewed during HREC certification by the NHMRC (see Section 5). The decision must be ratified at the next HREC meeting, in order for the HREC Approval letter to be issued.
- 1.83. For prospective entry of data into a registry, an Information Sheet and Consent form will be required.
- 1.84. If the researcher wishes to access patient data retrospectively to enter it on the registry, consent will need to be obtained either from the patient involved, or via the *PHA* process.

Accessing data for the purposes of research, from an already existing Registry or Database

- 1.85. If a researcher wishes to access data from an already existing registry or database, the type of application form required and mode of review depends on the level of risk of the project, and whether multiple databases will be accessed for the project.
- 1.86. The Information Sheet and Consent form that was originally presented to the patients to allow entry of their data into the registry or database needs to be checked to see if consent was given for their data to be used for future research projects.
- 1.87. If no consent was obtained to enter data into the database or registry, or if the original consent form did not provide an opportunity to consent to research, a *PHA* must be completed to allow disclosure of unconsented potentially reidentifiable confidential health information for the purposes of research.

Research targeting Aboriginal and Torres Strait Islander Peoples

- 1.88. The *National Statement* chapter 4.7 and 5.16(b) requires these research projects to be reviewed by a full HREC regardless of the level of risk.
- 1.89. Research projects which specifically targets Aboriginal or Torres Strait Islander Peoples must be completed on a NEAF application.
- 1.90. As there is no certification category in the multi-centre review process for the review of multi-centre research targeting Aboriginal or Torres Strait Islander Peoples, multi-centre projects will not be submitted to the CCS for allocation to a Certified HREC. This research cannot be reviewed under the NMA model.
- 1.91. This means that multi-centre research targeting Aboriginal or Torres Strait Islander Peoples can be reviewed by any NHMRC registered HREC using the guidance provided in the *National Statement* chapter 4.7.
- 1.92. On receipt of a multi-centre research application targeting 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 advice from:
 - people who have networks with Aboriginal or Torres Strait Islander Peoples and/or knowledge of research with Aboriginal and Torres Strait Islander Peoples, and
 - people familiar with the culture and practices of the Aboriginal and Torres Strait Islander Peoples with whom participation in the research will be discussed.The HREC review must also consider whether the information that is in the NEAF will adequately represent all Aboriginal and Torres Strait Islander communities participating in the project.
- 1.93. It is the responsibility of the researcher to ensure that the RGO at all target sites will accept the review of an HREC that may not be the local HREC.

Withdrawal of Applications

- 1.94. If an applicant withdraws an application at any time, the application should be treated as no longer valid and the 60 calendar day time frame will no longer apply. The status should be marked

Withdrawn on *AU RED* and providing the file is in order, it can be archived. If the applicant wishes to re-submit the application at a later date, it should be treated as a new submission.

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

Research that may be exempted from HREC Review

- 1.96. *National Statement 5.1.22 – states that institutions may choose to exempt from ethical review research that:*
1. Is negligible risk research; and
 2. Involves the use of existing collections of data or records that contain only non-identifiable data about human beings.
- 1.97. The *National Statement s5.1.23* further states that *Institutions must recognise that in deciding to exempt research from ethical review, they are determining that the research meets the requirements of this National Statement and is ethically acceptable.*
- 1.98. Where the HREC Chair, HREC Administrator or RGO is approached for advice on whether a project falls within the definition of research, and does or does not require ethical review, the applicant should be advised to:
- consult the NHMRC *National Statement on Ethical Conduct in Human Research (2007)*; and
 - provide an outline of the project in writing to the HREC Chair justifying why they are seeking exemption from HREC review.
- 1.99. It must be noted that research that involves the use of data that is stored in an identifiable form cannot be used in research that i.e. exempt from ethical review (*National Statement 3.2.10*).

Quality Activities

- 1.100. An activity where the primary purpose is to monitor or improve the quality of service delivered by an individual or an organisation is a Quality Assurance activity. Terms such as 'peer review', 'quality assurance', 'quality improvement', 'quality activities', 'quality studies' and 'audit' are often used interchangeably and are considered part of a Quality Assurance program.
- 1.101. An HREC will frequently be presented with a project that is clearly a Quality Assurance project (QA) However, undertaking a QA does not require HREC Approval even if an ethical opinion is sought. Quality assurance projects should be registered as per the Institutional Clinical Governance process.
- 1.102. Clinical governance is a requirement of the compulsory National Safety and Quality Health Service Standards and an associated Australian Health Service and Quality Accreditation (AHSSQA) Scheme. <http://www.safetyandquality.gov.au/wp-content/uploads/2011/09/NSQHS-Standards-Sept-2012.pdf>
- 1.103. Clinical Governance approval is required for these activities, not Research Governance authorisation.

- 1.104. If an ethical opinion is sought then local institutional practice may include delegating responsibility to:
- A QA/low-risk committee
 - A sub-committee of the HREC
 - The HREC Chair or appropriate HREC member(s)
 - Another appropriate committee or individual involved in / responsible for clinical governance
- 1.105. If the delegated responsibility sits with a member of the HREC, then the researcher should be advised to liaise with the HREC Chair as to the documentation required, but as a minimum, a cover letter, a description of the project and project documentation that has been registered as part of the Institution's Clinical Governance process, along with the intended article for publication, should be submitted for review by the HREC Chair. It is not necessary for an LNR Application to be submitted.
- 1.106. The project is registered on *AU RED* and given an HREC number but should be categorised as a QA project.
- 1.107. The HREC Chair will review the submitted documentation and do one of the following:
- appraise the project, and issue a letter stating that it is a Quality Assurance project and does not require full HREC review and give an ethical opinion; or
 - appraise the project and require it to be submitted for review by the HREC or LNR Committee. If it is considered that the project is not a QA, or if parts of the project have been conducted outside the scope of a QA, a NEAF or LNR form must be completed and submitted with the application.
- 1.108. Research governance authorisation is not required unless the project is considered research or has a research component.

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

- 1.109. HRECs will often be asked to provide an approval for presentation of un-consented confidential health information for conference presentations or for publication in professional journals. If confidential information is disclosed without the consent of the person who the data relates, an application under the *Public health Act 2005* should be made. A letter from the HREC must be generated
- 1.110. This is an example of where the RGO should waive the requirement of SSA form completion.

Accepting the HREC Review for Studies not included in the National Mutual Acceptance model or from a Non - Certified Committee

- 1.111. If a research project has been reviewed and approved by an HREC 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 HREC at their institution only.

- 1.112. Section 5.3 of the *National Statement* endorses minimisation of duplication of HREC review and provides guidance on the processes to be followed.
- 1.113. The researcher should discuss with the HREC Chair via the HREC Administrator, the possibility of acceptance of the original HREC review. All documentation provided to the original HREC must be supplied to the HREC Chair for consideration.
- 1.114. The HREC Chair will review the application, bearing in mind any local circumstances relevant to the project.
- 1.115. If the HREC Chair accepts the project and study documentation without need for amendment, the study can be accepted, and this decision will be tabled at the next HREC meeting. The HREC Administrator will issue an HREC Approval Letter after the HREC has ratified the Chair's decision, or as per local HREC processes.
- 1.116. Research governance processes must be undertaken in the normal manner.
- 1.117. If the HREC Chair decides that amendments to the submitted protocol or study documentation are required, the project may be referred for full HREC review. This does not apply to administrative amendments.
- 1.118. All reporting to the HREC is made to the Local HREC.

Exceptional Circumstances Review

- 1.119. 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.
- 1.120. An application for review under exceptional circumstances is never justifiable solely on the grounds of a researcher's claim to the need for urgent review of their project based on failure to meet deadlines.

Single Site "Exceptional Circumstance" Studies

- 1.121. Applications submitted for review under exceptional circumstances should contain:
 - a completed Online Forms version of the application form or another format if time does not allow for the Online Forms application to be completed; and
 - study protocol and supporting documentation; and
 - a written request for an exceptional circumstance review, which explains the reason for requesting review and justification for the request.
- 1.122. The application will be checked by the HREC Administrator for compliance with application procedures and recorded on *AU RED*.
- 1.123. The application will be reviewed by the HREC Chair and one or more HREC member/s. The Chair and additional HREC member/s will be blinded to the other's decision in the initial review. One of these reviewers should be a layperson or other member not affiliated with the institution. The

reviewers will be given the opportunity to seek clarification from the investigator or from other HREC members, if required, prior to making a decision.

- 1.124. If the decision of the Chair and additional HREC member/s is unanimous that the application qualifies for exceptional circumstance review, the HREC Chair will advise the HHS CE or delegate, and the local RGO, of the recommendation to conduct the research and monitoring responsibilities. The local RGO may waive the requirement to complete the SSA and document CE approval in any way.
- 1.125. If there is disagreement between the Chair and the additional HREC member, the protocol will not receive exceptional circumstance review and will be reviewed by the full HREC.

Multi-centre “Exceptional Circumstance” Studies

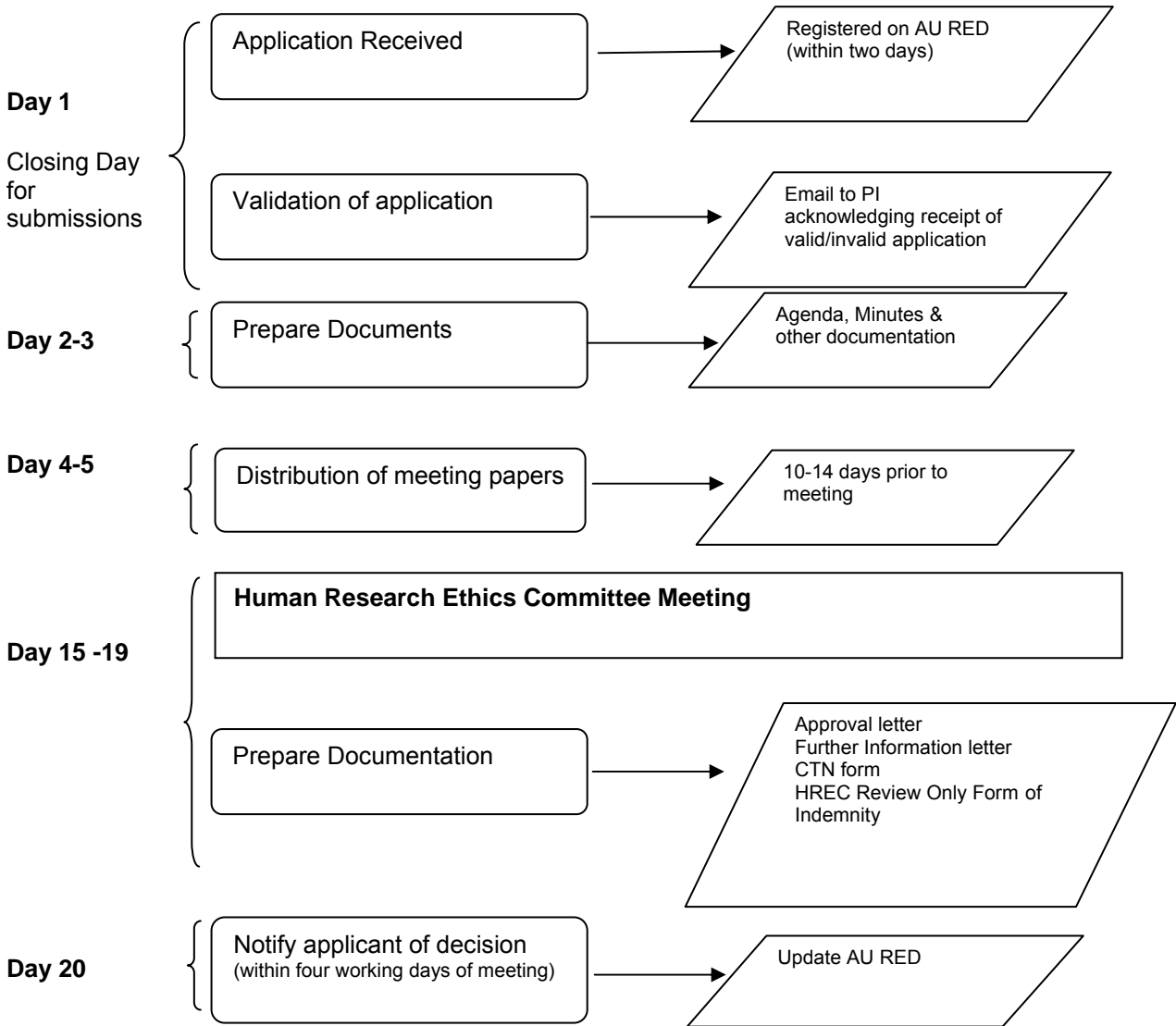
- 1.126. The study must be submitted for single ethical review through the Queensland Department of Health CCS with a request for review under exceptional circumstance. The process for review is as outlined above.

Requests for Retrospective Research Approvals

- 1.127. There is no such thing as a retrospective research approval.
- 1.128. If an HREC Administrator is presented with a request for retrospective approval of research work already completed, the following advice should be given to the researcher:
- 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
 - An application must be presented to the full HREC
 - The HREC may request changes to the project before the completed work is published or presented, or may request the entire project be repeated
 - An *Approval Letter* cannot be issued. However, the HREC can issue an *Acknowledgement* of the project undertaken without review and can include that the completed presentation was reviewed by the HREC prior to publication / presentation.

HREC Review Process Flow Chart

20 DAY HREC PROCESS



SECTION 2: Meetings of a Human Research Ethics Committee

General Guidance

- 2.1. All validated applications requiring HREC review should be considered at a scheduled meeting of an NHMRC Registered HREC, held in accordance with the following procedures.
- 2.2. Procedures relating to the outcome of the ethical review, including the decisions available at meetings and the request for further information or clarification following the meeting, are set out in Section 3.

Meeting schedules

- 2.3. An HREC should hold regular scheduled meetings of the full committee in each year for the purposes of ethical review of applications as per *The National Statement*, Section 5. Most HRECs meet monthly.
- 2.4. However whatever the frequency of meetings, the HREC must ensure that an ethical decision on an application is given within the time limit of 60 review days from the date of receipt, to discuss matters relating to the establishment or operating procedures of the HREC or for training purposes.
- 2.5. The schedule of Committee meetings for the year commencing on 1 January should be agreed between the HREC Administrator and the HREC Chair by 31 October in 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 calendar days prior to each meeting) and the number of application copies required for submission. All members of the HREC should be issued with details of the schedule. This requirement applies also to meetings of any Sub-Committees.
- 2.6. Following approval by the HREC Chair, the HREC Administrators should arrange for the HREC membership, HREC Terms of Reference and meeting schedules to be publicly accessible. Copies of these documents are to be provided to the CCS for the purpose of updating the website.

Agenda

- 2.7. The HREC Administrator prepares the agenda for the meeting, which should include at least the following:
 - the date, time and venue of the meeting;
 - minutes of the previous Committee meeting;
 - business arising from the previous meeting(s) that the Committee specifically indicated that it wished to consider again;
 - new applications to be considered at the meeting;
 - amendments to previously reviewed documents;
 - any mandated reports such as annual progress reports, safety reports or final study reports and other items for noting by the committee;
 - notice of upcoming educational activities that may be of interest to committee members;
 - any General Business; and

- notification of the date, time and venue of the next scheduled meeting.
 - All documentation sent to HREC members should be individually numbered by agenda item.
- 2.8. Where it is the local procedure to appoint a lead reviewer(s), the agenda should indicate the lead reviewer(s) for each application.
- 2.9. The agenda may also include discussion of the following where appropriate:
- general research ethics issues e.g. new guidelines or recent publications;
 - matters relating to the establishment or membership of the HREC; or
 - matters relating to HREC procedures.
- 2.10. It is important that HREC meetings include sufficient applications to maintain the expertise of the Committee and justify the resources involved, but not so many as to compromise the rigour of the ethical review.
- 2.11. 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.
- 2.12. Where the HREC has previously delegated authority to the Chair to give an ethical 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.
- 2.13. After the meeting, the following information should be recorded in *AU RED*:
- the ethical decision given on the application;
 - the members who were involved in confirming the ethical decision of the Committee; and
 - whether any questions of ethical consideration arose during the out of session review of the study.
- 2.14. A brief summary should be given of the applicant's response and the reasons for the decision taken.

Lead reviewers

- 2.15. An HREC may appoint one or more members as lead reviewers for each application.
- 2.16. Allocation of applications to lead reviewers may be made by the HREC Administrator, in consultation with the Chair.
- 2.17. 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 members.

Distribution of papers for meetings

- 2.18. The HREC Administrator should arrange the distribution of the agenda, applications and other relevant papers for review at the meeting between 10 and 14 days prior to the meeting.
- 2.19. Under no circumstances should late new applications (i.e. those submitted after the HREC closing date) be tabled at the meeting, except as described under Exceptional Circumstances (1.09), or in other exceptional circumstances, with the agreement of the Chair, certain papers may be tabled at the meeting.

- 2.20. All members should receive a copy of the appropriate application form for each new study, together with all supporting documentation with the following exception:
- 2.21. The Investigator Brochure for an investigational product / device should be sent only to members with relevant expertise (in particular, to physician / pharmacist / interventionist / surgeon), lead reviewers or to all members if so requested.
- 2.22. Attach a comments sheet to each new application, on which the committee member may record his / her comments.

Attendance of the PI or CPI

- 2.23. At the request of a committee member after discussion with the HREC Chair, 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 meeting is for the PI (or CPI for multi-centre studies) to respond directly to requests from the Committee for further information, clarification or reassurance.
- 2.24. Where the PI (or CPI for multi-centre studies) is 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 or CPI. Other members of the research team or representatives of the sponsor may also express an interest in attending alongside the PI (or CPI for multi-centre studies) and may do so at the discretion of the Chair.
- 2.25. In the case of applications submitted by students, the HREC may consider inviting the academic or clinical supervisor.
- 2.26. It is not the purpose of the PI's (or CPI for multi-centre studies) attendance to make a formal presentation of the study, and this should not be permitted.

Minimum membership requirements and meeting attendance

- 2.27. The minimum membership for meetings of an HREC is eight members (quorum), as specified in paragraph 5.1.29 & 5.1.30 of *The National Statement*.
- 2.28. Where there is less than a full attendance of the minimum membership at a meeting, the meeting may proceed provided the Chair is satisfied that the views of those absent who belong to the minimum membership have been received and considered - as stated in paragraph 5.2.30 of *The National Statement*. The HREC Administrator should present all comments / views submitted by absent members as appropriate during the meeting.
- 2.29. An HREC should appoint more than the minimum membership to ensure a quorum at all meetings.
- 2.30. If paragraph 5.2.30 of *The National Statement* has not been satisfied, the Committee may not commence, continue or conclude any discussion with the purpose of determining the Committee's decision on an application for ethical review. However, the Committee may proceed with any other business on the agenda as if it were a sub-committee meeting, provided that the Chair (or Deputy-Chair or alternate Deputy-Chair) and at least one other member is present
- 2.31. The HREC Administrator should keep a record of attendance, indicating which members were present for the discussion of each application for ethical review.

- 2.32. Where an 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.

Actions to be taken if minimum membership requirements are not met

- 2.33. Where the HREC Administrator is concerned that a forthcoming meeting may not be attended by the minimum membership due to foreseen absences, he / she should report the matter to the Chair and consider the following options:
- contacting members who will be absent from the meeting to obtain an opinion on the items for discussion ahead of the meeting;
 - alternate members who have the necessary expertise to fulfil the membership criteria;
 - postpone and re-arranging the meeting; or
 - cancel the meeting.
- 2.34. If the meeting is postponed or cancelled, the HREC Administrator should consider with the Chair the need to ensure that the applications listed on the agenda are processed within the recommended time limit. Other measures such as email comments from absent members may be utilised taking into account the recommendation set out in *The National Statement* s5.2.30.
- 2.35. Researchers must be notified of the changed arrangements for the HREC review if the meeting is cancelled or postponed, and given the option to withdraw their application and submit elsewhere.

Written comments from members

- 2.36. A member who is unavailable to attend a meeting may submit comments in writing on any agenda item.
- 2.37. The Minutes should record the submission of written comments in the Attendance Record, along with a notation that the member was absent from the meeting.
- 2.38. A member who submits written comments but does not attend the meeting counts towards the quorum.

External Expert Reviewers

- 2.39. An HREC may seek the written advice of an expert reviewer on any aspects of an application that are relevant to the formation of an ethical decision, and which lie beyond the expertise of the members or on which the Committee is unable to agree. This may necessitate going outside the membership of the HREC. These expert reviewers may be specialists in ethics, specific diseases or methodologies, or they may be representatives of communities, patients or special interest groups.
- 2.40. For multi-centre research, the opinion of the external expert may NOT be used to allow the HREC to review research outside of its NHMRC certification categories.
- 2.41. For commercially sponsored studies the cost of the external expert review may be borne if agreed, by the sponsor.
- 2.42. Advice from expert reviewers may be sought at any time by the HREC.
- 2.43. A list of external expert reviewers is available from HMR.

- 2.44. Expert reviewers are not voting members of the HREC, and should not be involved in the business of the Committee other than that related to the application on which their advice is sought.
- 2.45. The HREC Administrator or Chair should ensure that the expert reviewer(s) has / have declared any conflict of interest and agreed to Queensland Department of Health Terms of Confidentiality
- 2.46. If possible, a copy of the advice received should be made available to members prior to the meeting or tabled at the meeting. The substance of the advice should be recorded in the Minutes.
- 2.47. The external expert reviewer may be invited to attend the meeting in person for discussion of the application concerned

Procedure for obtaining advice from an External Expert Reviewer(s)

- 2.48. Where an HREC decides that it cannot give a decision until it has obtained further advice from an external expert reviewer (EER), 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 expert reviewer;
 - the letter / email may notify the applicant of the issues of concern to the HREC, but should not at this point request further information or clarification.
- 2.49. In some cases, the HREC may decide at the meeting, whom it wishes to consult, and if so this should be recorded in the Minutes. If not, either the Chair or the HREC Administrator should be appointed to identify a suitable expert reviewer urgently following the meeting.
- 2.50. The Chair or HREC Administrator should initially contact the prospective external expert reviewer(s) by phone or email to establish whether he / she is willing and able to provide expert advice within the required timescale. It should be established that the prospective 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 forwarding the application for review.
- 2.51. Once a suitable expert reviewer has been identified, the HREC Administrator should formally write to the expert reviewer. This letter should be as specific as possible about the issues of concern to the HREC and the nature of advice required using any of the following forms for all clinical phase trials in these categories.
- 2.52. A copy of the application form should be provided, together with any supporting documentation required by the expert reviewer. Where possible, the letter should be sent within five working days of the meeting. The expert reviewer should be asked to respond in writing within a further 14 days.
- 2.53. Once the 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. 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.
- 2.54. The HREC should not disclose the nature of the reviewer's advice to the applicant. The decision the HREC reaches on the application is its own. The HREC may not disclose the identity of the reviewer / s except with his / her express permission.

Studies Requiring Queensland Civil and Administrative Tribunal (QCAT) Opinion

- 2.55. The PI (or CPI for multi-centre studies) is required to obtain approval from the QCAT in circumstances where the participant of the trial may be, by reason of physical or mental incapacity, incompetent to give informed consent to participate in the study. This approval process occurs after HREC approval and forms part of the governance process.
- 2.56. *The National Statement* (updated 2009) provides guidance on obtaining consent where incompetence to provide consent is considered to be
- temporary or
 - permanent.
- 2.57. Legal advice suggests that doubt exists as to whether a validly appointed substitute decision maker for personal matters, including health care of a person who lacks capacity (the person), can consent on behalf of the person for the disclosure of confidential information. A specific statement regarding the consent for disclosure is advised in the substitute consent statement. For the avoidance of any doubt a Queensland Health staff member will not be in breach of the *Hospital and Health Boards Act 2011* if they disclose confidential information without the written consent of the person to whom the data relates to where approval has been granted under the *Public Health Act 2005*.

What is impaired decision-making capacity?

- 2.58. It is the inability to go through the process of reaching a decision and putting it into effect. There are three parts to this process:
- understanding the nature and effect of the decision
 - deciding freely and voluntarily
 - communicating the decision in some way.
- 2.59. If a person is unable to carry out any of these, he/she is said to have impaired decision-making capacity, whether the impairment is the result of congenital intellectual disability, acquired brain injury, dementia, mental illness or some other cause.
- 2.60. Sections 65, 68, 72 and 74 of the *Guardianship and Administration Act 2000* cover participation in “special medical research or experimental health care”.
- 2.61. For persons under the legal age of consent, written approval must be obtained from the person’s parent(s) or guardian(s). Where a person is over the legal age of consent but is unable to provide informed consent for participation, written application to the QCAT must be undertaken.
- 2.62. Approval from QCAT does not provide consent for a person who has impaired decision making capacity to participate in a research project. QCAT Approval determines whether a clinical trial is appropriate for a person of impaired decision making capacity to participate in. However, consent for participation is still required from the Legally Authorised Representative (LAR)
- 2.63. It must also be noted that consent for participation from the LAR does not include consent for release of the person’s confidential information. A *Public Health Act 2005* approval is required for the release of confidential information for research where there is not the written consent of the person to whom the data applies.

2.64. The Queensland Civil and Administrative Tribunal contact details are:

Queensland Civil and Administrative Tribunal
GPO Box 1639

Brisbane Qld 4001

T: 1300 753 228

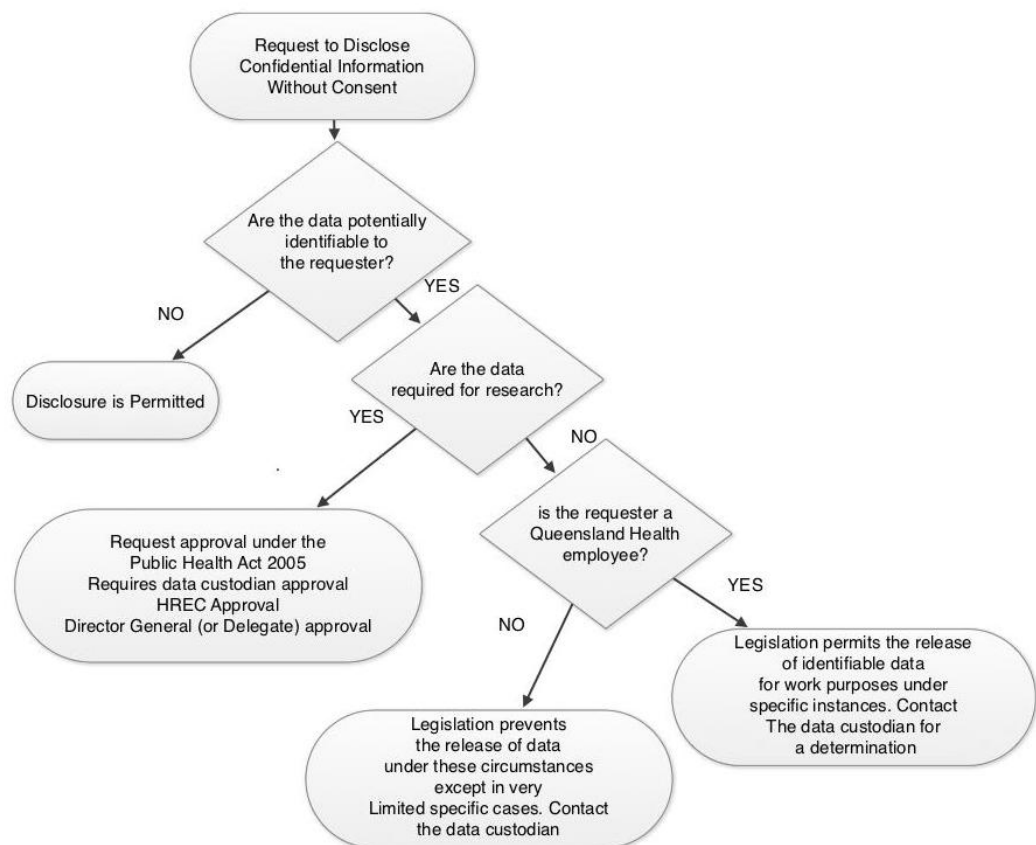
F: 07 3221 9156

E: enquiries@qcat.qld.gov.au

<http://www.qcat.qld.gov.au/>

<http://www.qcat.qld.gov.au/matter-types/guardianship-for-adults-matters/application-process>

The *Public Health Act 2005* (Qld) ('PHA') and Studies Requiring Access to Confidential Information held by Queensland Health



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

2.66. s144 states that confidential information can be disclosed if the information is related to an adult and they have consented to the disclosure. If the information is related to a child, the parent or guardian must consent and the child must consent if the health professional believes the child is of sufficient age and mental and emotional maturity to understand the nature of consenting to the

disclosure. If the child is not capable of consent, then the Health Professional must reasonably believe the disclosure of the information is in the child's best interest.

- 2.67. s143(1) further states that a designated person *may* disclose Confidential Information if the disclosure is required or permitted by an Act or law.
- 2.68. The *Public Health Act 2005* (Qld) ('PHA') is the instrument by which confidential health information may be accessed for the purposes of research - as it is defined in the PHA.
- 2.69. When researchers require access to and use of potentially re-identifiable data and confidential information for the purposes of research, without the consent of the person to whom the information relates, an application must be made under the PHA, s281-284 to allow the data custodian to disclose the confidential information without breaching the *Hospital and Health Board Act 2011*.
- 2.70. The *Public Health Act 2005* s280 describes the types of investigations falling within its definition of research as being:
- a biomedical study (a study of the biological determinants of health and disease that establishes the biological basis for preventing, treating and curing disease) e.g. laboratory based research, genetic research;
 - a clinical and applied study (a study of the effectiveness of strategies to diagnose and treat disease or illness) e.g. clinical trials;
 - an epidemiological study (a study of the distribution and determinants of health related state or events in particular populations) e.g. cross-sectional study;
 - an evaluation and planning study (a study for appraising or measuring the value of a health intervention; or designing and projecting current and future health services) e.g. evaluation of a health promotion program; or
 - a monitoring and surveillance study (a study for keeping watch over the health of the population or individuals to control the spread of disease and maintain health and well-being) cohort study.
- 2.71. Legal advice suggests that doubt exists as to whether a validly appointed substitute decision maker for personal matters, including health care of a person who lacks capacity ('the person'), can consent on behalf of the person to the disclosure of confidential information for purposes such as research, quality assurance, professional development, teaching and training. This conclusion is based on the premise that research, quality assurance, professional development, teaching and training do not neatly fall within the definition of 'health care'.
- 2.72. A specific statement regarding the consent for disclosure is advised in the substitute consent statement. For the avoidance of any doubt a Queensland Health staff member will not be in breach of the *Hospital and Health Boards Act 2011* if they disclose confidential information without the consent of the person to whom the data relates to where approval has been granted under the *Public Health Act 2005*.
- 2.73. Legal advice suggests that an *Opt Out* approach to consent cannot be relied upon as consent and a PHA application will be required.
- 2.74. PHA application form must be completed and submitted to HMR for consideration and approval, prior to governance authorisation being granted. Go to:
http://www.health.qld.gov.au/ohmr/html/regu/aces_conf_hth_info.asp

- 2.75. All research projects requesting a waiver of the requirement for consent must be reviewed by an HREC, as per s282(2)(i) of the *PHA*.
<http://www.legislation.qld.gov.au/LEGISLTN/CURRENT/P/PubHealA05.pdf>
- 2.76. The decision to grant the waiver of consent must be recorded in the HREC Approval letter.
- 2.77. Examples of research that may seek consideration for a waiver of the requirement of consent are:
- Accessing potentially identifiable data from data sets – *PHA* required
 - Accessing participant records – *PHA* required
 - Accessing identifying tissue from tissue banks – *PHA* required.

Issues about Consent

Granting a Waiver of Consent

- 2.78. In some cases, a researcher may apply to the HREC for approval of a waiver of consent for use of confidential information for research. This application may be made on either a NEAF or LNR Form.
- 2.79. The decision to grant the waiver of consent can only be made by a full HREC as per *The National Statement* s2.3.5.
- 2.80. An LNR subcommittee cannot grant a waiver of consent. LNR projects requiring access to identifiable or potentially re-identifiable confidential health information without consent must be submitted for review to a full HREC.
- 2.81. The decision to grant the waiver of consent must be recorded in the HREC Approval letter.
- 2.82. Examples of research that would qualify for consideration of a waiver of consent (from the individual) are:
- Accessing potentially identifiable data from data sets – *PHA* required
 - Accessing patient records – *PHA* required
 - Accessing tissue from tissue banks – *PHA* required.
 - Involving patients with impaired decision making capacity in a project that involves experimental treatment – QCAT Approval required and *PHA* required for disclosure of data

Obtaining Consent from a Proxy / Substitute or Legally Authorised Representative

- 2.83. 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 at the *Legally Authorised Representative*. This is irrespective of the type of research being undertaken.
- 2.84. Where the project includes experimental treatment, the researcher must also apply to the Queensland Civil and Administrative Tribunal (QCAT) after HREC Approval for the project has been obtained.
- 2.85. Please also see 2.67 – 2.74 in this section.

Conditions for the Granting of an *Opt Out Consent* also called *Prospective Waiver (Opt Out)* consent

- 2.86. Researchers may request an *Opt Out* approach to consent. This request must be made using a NEAF.
- 2.87. The application must only be considered by the full HREC (hence the term prospective waiver).
- 2.88. Potential research participants must be given a comprehensive Information Sheet, which clearly outlines their *opt out* options. The process must be clearly written up in the participants' medical notes.
- 2.89. Researchers must explain in the application how, if an *opt out* form is not returned, they will differentiate between *opting in* to the project and apathy or misunderstanding of the process by potential research participants.
- 2.90. If an *Op Out Consent* process is used then a *PHA* application must be made as confidential health information will be used without the consent of the person to whom the data relates.

Witness to the Consent

- 2.91. Generally it is not a requirement for a consent form to be countersigned by a witness.
- 2.92. GCP 4.8.9 provides the following guidance for the requirements for a witness to a consent:
If a subject is unable to read or if a legally acceptable representative is unable to read, an impartial witness should be present during the entire informed consent discussion. After the written informed consent form and any other written information to be provided to subjects, is read and explained to the subject or the subject's legally acceptable representative, and after the subject or the subject's legally acceptable representative has orally consented to the subject's participation in the trial and, if capable of doing so, has signed and personally dated the informed consent form, the witness should sign and personally date the consent form. By signing the consent form, the witness attests that the information in the consent form and any other written information was accurately explained to, and apparently understood by, the subject or the subject's legally acceptable representative, and that informed consent was freely given by the subject or the subject's legally acceptable representative (sic).
- 2.93. 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 (*National Statement 94.5.6*). 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.
- 2.94. It must be understood that the witness is not simply witnessing the signing of the consent document, but is attesting to the entire consenting process – that the information in the Information Sheet and Consent form and any other written information 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.

Declarations of Conflict of Interest

- 2.95. Members should declare to the Committee any interests they may have in relation to an application for ethical review or any other matter for consideration at the meeting.
- 2.96. Such a declaration may be made:
- orally at the meeting;
 - prior to the matter being considered; or
 - in writing to the Chair prior to the meeting.
- 2.97. Where the member concerned is the PI or another key investigator / collaborator named on the application form, the Committee should not proceed with the review until the member has excused himself / herself from the meeting room. If necessary the member can be invited back into the room to answer questions raised by the Committee, but should again leave the room when the discussion and deliberations resume.
- 2.98. In the case of any other declared interest, the Committee should collectively consider whether or not it is appropriate for the 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 interest may in itself be sufficient to ensure that the decision of the Committee is not unduly influenced.
- 2.99. The Minutes should record any declaration of conflict of interest and the decision of the Committee on the procedure to be followed.
- 2.100. Any conflict of interest pertaining to researchers, Institutions, HREC members and all other stakeholders should be considered in accordance with Queensland DoH Standard 5: Conflict of Interest in Research 2012 and the Queensland DoH Research Management Policy and associated Directive 2013.

Confidentiality of Proceedings

- 2.101. HREC members do not sit on the Committee in any representative capacity and 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.
- 2.102. The Terms and Conditions of Appointment for members include requirements to keep confidential the business of the HREC.
- 2.103. It is permissible for members of other HRECs to approach the HREC Chair to request permission to attend a meeting as an observer after signing a confidentiality agreement.

Conduct of Business and Decision-Making

- 2.104. The Chair is responsible for the conduct of the business and for ensuring that the Committee reaches clearly agreed decisions on all matters. Where the Chair is unavailable, the meeting should be Chaired by the Deputy Chair or, if the Deputy Chair is also unavailable, by another member, as determined by the Chair.

- 2.105. All members present, both expert and lay, should be allowed reasonable opportunity to express relevant views on matters on the agenda. As per s2.25 the written opinions of absent members should be tabled at the meeting and considered as part of the deliberation of a research project.
- 2.106. The HREC should endeavour to reach decisions by general agreement (paragraph 5.2.31 of *The National Statement*). Generally the Minutes will record discussion of significant issues and the decision given.
- 2.107. Where any member wishes to record his / her formal dissent from the Committee's decision, this should be recorded in the Minutes.

Responsibilities of the HREC Administrator

- 2.108. The secretary to the meeting will be the HREC Administrator or delegate.
- 2.109. The responsibilities of the Administrator in relation to HREC meetings includes the following activities:
- publishing the schedule of HREC meetings;
 - preparing the agenda
 - allocating lead reviewers - in conjunction with the HREC Chair (where this is the practice of the HREC);
 - distributing the agenda and papers;
 - inviting PIs and, where appropriate, supervisors to attend the meeting and making the necessary arrangements;
 - preparing the venue;
 - recording apologies for absence prior to the meeting;
 - raising with the Chair any concern that a meeting may not be quorate;
 - recording attendance by members and referees for the discussion of each application for ethical review;
 - advising the meeting as necessary on compliance with standard operating procedures;
 - taking and preparing the Minutes of the meeting for review and approval at the following meeting;
 - notifying applicants of decisions given at the meeting (within four working days) and attending to other follow-up action as necessary;
 - organise for the HREC Chair to sign the CTN forms; and
 - organise for HHS CE / delegate to sign HREC Review Only Form of Indemnity where necessary.

Minutes

- 2.110. The Minutes of the HREC meeting should be prepared by the HREC Administrator in consultation with the Chair and other members as necessary, and approved by the Chair within three days following the meeting.

- 2.111. The Minutes of the HREC meeting should be uploaded and saved in *AU RED* under the Correspondence tab for the relevant meeting.
- 2.112. In relation to applications for ethical 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:
- the members and external expert reviewers present for the review;
 - any conflicts of interest declared, and the decision of the Committee regarding allowable level of participation of the member concerned;
 - the submission of written comments by members;
 - the substance of any advice given by an expert reviewer;
 - the decision of the HREC regarding the application;
 - a summary of the main ethical issues considered and referenced to *The National Statement*;
 - 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;
 - in the case of a Not Approved decision, the reasons for the decision with reference to *The National Statement*;
 - where the opinion of an external expert is sought, the issues on which further advice is required; and
 - any formal dissent from the decision of the HREC by a named member, with reasons for their dissent.
- 2.113. 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 Chair.
- 2.114. The Minutes are confidential to the HREC and should not be disclosed to applicants, sponsors or host organisations.
- 2.115. For the purposes of HREC governance, copies of Minutes should be made available to the appointing authority for the HREC according to the local *Terms of Reference*.
- 2.116. The Executive of the Authority (HHS CE / delegate) should be provided with an Annual Report which contains details of applications made to the HREC – not just Approved applications – and any other requested information required for HHS / Institutional reporting.

SECTION 3: Determining an Ethical Decision

- 3.1. An HREC is required to give an ethical decision on a submitted application within 60 review days (excluding stop clock days) of the receipt of a valid application. Where the HREC considers that further information is required in order to give a decision, the HREC may request, in writing, further information from the applicant. The period of 60 days will be suspended pending receipt of this information.
- 3.2. If the HREC is unable to give a final decision on an application within the 60 clock days review period, the following guidance is given:
- The HREC may, with agreement from the researcher, continue the review of the project, until such time as a decision is reached, or
 - The HREC gives the project a decision of *Not Approved* and the researcher is given the option of :
 - re-submitting a new application, with a new HREC number to the same committee; or
 - 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
 - withdrawing the application all together.
- 3.3. All HREC reviews exceeding 60 days are monitored by the Department of Health to assess if any remedial actions are required to be implemented. All metrics regarding HREC review are available to the public.

Decisions available to the HREC

- 3.4. An HREC should reach one of the following decisions on any application reviewed at a meeting:
- Final decision. The Committee may reach a final decision on the application at the meeting. This decision may be either:
- *Approved*; or
 - *Not approved*.
- Further information / modification requested. The Committee 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*. Do not give the application a decision of *Not Approved* at this time.
- After reviewing the requested clarifications, the outcome will be:
- *Approved*;
 - *Not Approved*; or
 - *Further information/modification requested*.
- No opinion pending consultation with referee. The Committee may decide that no decision can be given until an expert reviewer has been consulted.

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

Not requiring review by HREC. The Chair may decide that the application does not require review by the HREC (e.g. some Low and Negligible Risk research, quality assurance projects).

- 3.5. The Chair should ensure that one of the above decisions is recorded for every application considered at an HREC meeting.
- 3.6. 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.
- 3.7. In making an ethical decision, the 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 minuted at the next HREC meeting.

Notification of the Decision to the PI (or CPI)

- 3.8. The HREC Administrator should ensure that, following confirmation of the Minutes by the Chair, notification of the decision is sent in writing to the PI (or CPI for multi-centre studies) within four working days of the meeting. Initial notification to the researcher, of the HRECs decision, may be via email from the HREC Administrator or HREC Chair.
- 3.9. In all cases, the decision reached by the Committee should be communicated in the notification letter. The letter should also include:
 - those areas of concern for the Committee, for which further information is being requested; and
 - the HRECs decision on any issues for which the applicant has specifically requested an opinion.
- 3.10. The letter should not attribute particular comments or questions to individual members of the Committee.

Request for Further Information

- 3.11. Where the HREC decides that further information or clarification is required, the researcher is notified in writing about the requested clarifications.
- 3.12. The Chair should ensure that:
 - the further information or clarification required is specifically identified at the meeting;
 - the investigator should not be asked to submit a revised application form but should be asked to provide a cover letter clearly addressing the questions asked by the HREC and must provide all the revised documentation e.g. study protocol, participant information sheets and consent forms etc in both tracked changes and clean forms. All new documentation is to be uploaded against the original application form in *Online Forms*. New version details are required where appropriate;

- delegation of responsibility for considering the further information and confirming the HRECs final decision is clearly agreed, i.e. the information will need to be re-submitted to the full committee, a number of committee members or the Chair only; and
 - the questions asked by the HREC are based on references to *The National Statement*.
- 3.13. Requests for further information or clarification may include recommendations for revision of the terms of the application or any of the supporting documentation, for example the Participant Information Sheet and Consent Form (PICF).

Delegation of responsibility by the HREC

- 3.14. 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 CPI or PI which may include one of the following:
- delegation of authority to review the correspondence and approve the study between meetings at the discretion of the Chair alone;
 - delegation of authority to review the interim correspondence and approve the study between meetings at the discretion of an Executive of the HREC, comprising of one or more HREC members;
 - consideration of correspondence at a future meeting of the HREC; or
 - delegation of authority to the HREC Administrator (administrative amendments only).
- 3.15. 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.
- 3.16. 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 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 or a relevant expert member. Where these questions are likely to be significant, a sub-committee meeting should be arranged so that they can be fully discussed.
- 3.17. It may be decided that the response should be considered at a further meeting of the HREC. When taking this course, the HREC should take into account the 60-day clock time limit. If the researcher 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 60-day time Period

- 3.18. The 60-day review period should be suspended from the date on which the request for further information is sent to the applicant. It is automatically re-started when a valid response is registered on *AU RED*, not the date on which the information is considered by the HREC.

- 3.19. Where possible, the HREC should encourage informal communication with researchers, and should consider face-to-face meetings to resolve issues about research proposals that have not been resolved by written or telephone communication.
- 3.20. 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.

Final Decision following Consideration of the Information

- 3.21. 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 HRECs final decision

- 3.22. The final decision of the HREC will form part of the recommendation to the HHS CE for Authorisation to conduct the research at the site. The letter notifying the final decision of the HREC review should be communicated to the applicant no later than 60-day clock review days from the validation date.

When the Application is *Approved*

- 3.23. The HREC Approval letter should list the following items:
- a list of all documents reviewed at the meeting, giving version numbers and dates;
 - the list of sites for which the HREC decision is valid (multi-centre research only);
 - the period of validity of the HREC Approval;
 - the date on which the application was approved (noting that this will be different from the date on which the letter is signed);
 - specific reporting requirements for the study;
 - standard conditions for research approved by the HREC.
 - specific HREC Approval requirements e.g. the waiving of the requirement for consent;
 - advice regarding specific governance matters such as the requirement for a *PHA* or that the researcher contact the RGO with regards the possibility of a waiver of the requirement to complete an SSA Form, and
 - a de-identified list of the membership of the committee in attendance at the meeting at which the application was reviewed, (this includes the membership category, gender and institutional affiliation).
- 3.24. 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*

- 3.25. 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, as below.

Further review following a *Not Approved* decision

- 3.26. The researcher has the following options available:
- for single site studies, a new application may be submitted to the same HREC (and no other HREC), taking in to account of the HREC's concerns. This should be processed and reviewed in the same way as any other new application;
 - for multi-centre studies a new application must be submitted via the CCS, who will endeavour to allocate the study to the original reviewing HREC; or
 - the applicant may lodge a complaint with the HREC Chair and the process should be followed as outlined in Section 10.

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

- 3.27. Some research projects may be eligible for consideration of a modification to the process of research governance by waiving the completion of the SSA Form.
- 3.28. The decision to waive completion of the SSA Form is made by the RGO at each site, after discussion with the researcher.
- 3.29. Waiving of the completion of the SSA Form does not remove the requirement for research governance or CE authorisation to conduct the project in a HHS.
- 3.30. Notification to the researcher to discuss the potential for the waiving of the completion of the SSA Form is by the HREC Approval letter. The HREC Administrator may modify the HREC Approval letter to suggest the researcher liaise with RGOs at each research site to discuss the possibility of a modified research governance process.
- 3.31. It is the RGO at each site who will make the determination of eligibility for the modified process. The role of the HREC Administrator is to *inform the researcher* to discuss their eligibility for the modified RGO process with the site RGOs.
- 3.32. There are two separate procedures in place where the requirement to complete an SSA Form for each participating site may be waived - with the agreement of the RGOs at each participating site:
- *Minimum impact, minimum resource use research* (e.g. hanging a recruitment poster for an HREC Approved research project, but where all follow up is outside Queensland Health). Projects like this may be eligible for waiving the completion of the SSA Form.
 - *Minimum resource use research* – where the total contribution from the Queensland public institution is one hour or less – e.g. 10 minute survey targeting 6 or less staff at each site. Projects like this may be eligible for *state-wide minimum impact* SSA review process so that only one SSA form is submitted for all participating sites.

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

- 3.33. Where any HREC approval is given to a research project where the only resource impact is the data custodian releasing data to a researcher who is not an employee of Queensland Health, there is no requirement for research governance authorisation, as there is a legislative basis for the release of the data.
- 3.34. The Data Custodian has to agree to the disclosure of the data and may charge a fee if the resource impact is too great.
- 3.35. A register of all PHA applications is maintained by the Department of Health.

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

- 3.36. Where the researcher is an employee of Queensland Health, , the RGO may waive the requirement for completion of an SSA form, and can issue an Authorisation Letter provided the researcher has a PHA approval and has provided a copy of the PHA Approval Letter. Please refer to Guidance for the Potential Waiving of SSA Form above.

Matters relating to the Confirmation of an Approved Decision

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

- 3.37. HRECs play an important role in the regulation of the supply of unapproved goods under the *Therapeutic Goods Act 1989* in connection with the operation of clinical trials (both the *Clinical Trial Notification (CTN)* and *Clinical Trial Exemption (CTX)* schemes), the *Special Access Scheme* and approval of *Authorised Prescriber*.
- 3.38. Unapproved therapeutic goods have undergone little or no evaluation of quality, safety or efficacy by the Therapeutic Goods Administration (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 and precautions in research involving humans.
- 3.39. The roles and responsibilities required of HRECs under the Therapeutic Goods legislation can be found at: <http://www.tga.gov.au/hp/access-hrec.htm>
- 3.40. This section should be read in conjunction with *The National Statement*, Chapter 3.3: Interventions and Therapies, including clinical and non-clinical trials, and innovations and *Good Clinical Practice (GCP) Guidelines*.
- 3.41. In particular, the following should be noted:
 - the difference between the CTN and CTX schemes is the level of involvement of the TGA in reviewing data about the therapeutic good involved in the trial before the trial begins;
 - 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;

- CTX: The TGA reviews summary data about the therapeutic good (medicine or medical device) The CTX scheme approves usage guidelines and any number of protocols can be conducted within the scope of those usage guidelines;
- HRECs are responsible for reviewing clinical trial protocols for both CTX and CTN. 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;
- in approving a trial protocol, under both the CTN and CTX schemes, the HREC is assuming responsibility for monitoring the conduct of the trial. In signing the CTN and CTX form they are agreeing to this responsibility;
- original signatures must be provided on the CTN / CTX form;
- for multi-centre research, there will be a separate CTN / CTX form for each site participating in the research unless the Sponsor has provided a collated form with individual site pages inserted into Sections two and four; and
- For multi-centre research, it is recommended that the CTN forms are submitted with the HREC application and are signed by the HREC first. The CTN Forms may then be returned to the CPI for onward processing.

3.42. There is no set order for the collection of signatures on the CTN / CTX form, except for the Sponsor of the trial who always signs the CTN or CTX form last, as per the instructions on the form.

Indemnity

3.43. For any research that is conducted external to the HRECs Institution, indemnity for the HREC review will be required.

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

3.45. The HREC Administrator should encourage the researcher to discuss the level of indemnity with the HHS CE prior to validation of the HREC application.

Commercially Sponsored Research

3.46. For commercially sponsored research, the Medicines Australia *Form of Indemnity – HREC Review Only* must be submitted with the HREC Application. 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 Insurance must accompany this Form of Indemnity.

3.47. The Medicines Australia *Form of Indemnity – Standard* may be used when there is only one site participating in the commercially sponsored project, 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.

- 3.48. The HREC Administrator should liaise with the site RGO to determine local processes for CE execution of the Forms of Indemnity.
- 3.49. The HREC Approval Letter should not be released until the *Form of indemnity - HREC Review Only* is executed.
- 3.50. Refer to Queensland DoH Research Management Policy (2012) and Directive (2013).

Investigator Initiated Research

- 3.51. HREC Indemnity:
- When assessing an Investigator Initiated research project, indemnification of the HREC is provided by the Sponsor of the project or their employer.
 - The level of risk of the project will influence the degree of indemnification required.
 - Each Institution is responsible for determining its own level of acceptable risk and the indemnification requirements, for the HREC, for that level of risk.
- 3.52. Site Indemnity:
- The level of risk of the research project will influence each HHS's decision whether or not to provide indemnity for an Investigator Initiated research project, or to expect their researchers to be indemnified by a contracted party to the project.
- When required, the Medicines Australia *Forms of Indemnity* – used without amendment – are the preferred Indemnity documents.

Collaborative Research Groups

- 3.53. Medicines Australia has developed a research contract specifically for Collaborative Research Groups. There is an indemnification clause in the contract that states:
- *Each party is liable for its acts and omissions in relation to the conduct of the Study.*
 - *Each party must maintain such insurances as are reasonably available and necessary to provide indemnity to it in relation to any liability which it may incur in conducting the Study or performing its obligations under this Agreement.*
 - *The Institution satisfies the requirements of clause 11.2 if it is entitled to indemnity under a program or scheme of insurance or indemnity that is arranged by a State or Territory of the Commonwealth of Australia.*
- 3.54. Provided that there are no amendments to this clause in the contract, this Indemnity Statement is acceptable to the Queensland DoH and HHSs.

International Research operating under a Research Grant

- 3.55. Indemnification requirements as for Investigator Initiated research.

Insurance

- 3.56. Generally, Insurance is the domain of the RGO. However, the Form of Indemnity – *HREC Review Only* must be accompanied by an appropriate Insurance Certificate of Currency.

- 3.57. It is preferred that the Insurance Company has a representative office in Australia to enable rapid review and settling of any claims.
- 3.58. For sponsored clinical trials, the Sponsor or CRO is to indemnify the 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-compensation-guidelines/>
Please also refer to the Queensland DoH Research Management Policy 2012:
http://www.health.qld.gov.au/ohmr/html/regu/for_researcher.asp
- 3.59. Required Insurance:
- Clinical Trial/Product Liability insurance for an amount not less than \$10m AUD per claim;
 - Public liability insurance for an amount not less than \$10m AUD per claim;
 - Professional indemnity insurance for an amount not less than \$10m AUD per claim;
 - Workers compensation insurance in accordance with applicable legislation.
- 3.60. All insurance certificates must be valid at the time of submission for 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.

Confidentiality

- 3.61. 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.
- 3.62. No copies of letters should be sent directly by the HREC to the sponsor(s) of the research. All correspondence is between the CPI / PI and the HREC.
- 3.63. As per *The National Statement* s5.2.27 and 5.3.3, information regarding the review of a study may be exchanged between reviewing HREC.

Updated Safety Information

- 3.64. Section 3.3.23 of *The National Statement* lists circumstances where it may be unethical for a researcher to continue a trial. The HREC should inform the PI (or CPI for multi-centre studies) if they become aware of such circumstances.
- 3.65. In this instance, the study will be logged in *AU RED* as having been terminated. A note explaining the reason for the termination may be made in *AU RED* in the project's account.

SECTION 4: Amendments to Research Given HHS Authorisation

- 4.1. Investigators are required to obtain ethical approval and research governance authorisation before implementing any amendment to a previously authorised study.
- 4.2. Where a site specific amendment has no impact on the ethical acceptability of the study, the amendment should be discussed with the HREC and with their permission it may be submitted directly to the site RGO not require HREC review.

Processing of Amendments to a Research Project

- 4.3. The Site PI (or CPI for multi-centre studies) is required to submit amendments for approval to the Reviewing HREC.
- 4.4. Amendments should be outlined in a cover letter from the PI or CPI, stating the changes and reasons for changes, and accompanied by all relevant updated documents (which have been uploaded through the *Online Forms* website by the PI or 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 must be submitted to the HREC Administrator, as required as per normal HREC procedure.
- 4.5. The 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 Chair will be the spokesperson for the amendment. All amendment decisions must be noted on the agenda for the next HREC meeting.
- 4.6. The HREC will review the amendment request and may require further clarification or information regarding the amendment prior to granting approval.
- 4.7. The HREC will notify the CPI in writing of its decision.
- 4.8. The amendment cannot proceed until site authorisation is granted by the HHS CE via the RGO.
- 4.9. For commercially sponsored research, an amendment review fee may be charged unless the amendment is an Administrative Amendment.

Amendments for Urgent Safety Measures

- 4.10. Where it is necessary to eliminate an immediate hazard to the research participants, amendments to the research study may be implemented without prior HREC review and authorisation from the HHS CE / delegate (if necessary).
- 4.11. The Sponsor of the study must be notified immediately by the PI if the protocol amendment is due to urgent safety issues at the site.
- 4.12. As soon as possible, the implemented amendment should be submitted to the HREC and RGO.

Amendments requiring Submission of a New Application

- 4.13. 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 ethical review.
- 4.14. Examples might be where the proposed amendment involves:
- a change in the primary purpose or objective of the research, such as introduction of additional genetic sub-studies;
 - a substantial change in research methodology;
 - introduction of new classes of investigations or other interventions (rather than simply re-scheduling or modifying those already approved);
 - recruitment of a new type of participant (especially if these would be regarded as being from vulnerable groups); or
 - 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 re Amendments

- 4.15. The decision reached will be the same as those for new applications. See section 3.3

Expansion of a Research Study to an Additional Site/s

Single site studies

- 4.16. 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.
- 4.17. 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. The CPI will be required to contact the CCS to determine which HREC will review the application.
- 4.18. If the original Reviewing HREC is certified to review multi-centre research in the study field, the CPI 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*.
- 4.19. If the HREC Chair agrees to accept the additional site and take on monitoring responsibilities for a multi site study, the CPI will submit an amendment to the original reviewing HREC.
- 4.20. The Reviewing HREC will notify the CPI once HREC approval is granted.
- 4.21. If the HREC Chair does NOT agree to accept the additional site and amend the study from single site to multi site, the Investigator must contact CCS to organise for the study to be allocated to a new Reviewing HREC as a multi-centre study.
- 4.22. 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 clerk the study on *AU RED* as *Withdrawn by Researcher* and insert appropriate comment into the *Notes* section for that study in *AU RED*.

- 4.23. It is the responsibility of the CPI to notify the new PIs when HREC Approval has been granted. The PIs will then apply to their relevant RGOs for HHS governance authorisation.
- 4.24. The research will not be able to commence at each additional site until each respective HHS / site has granted authorisation.
- 4.25. For those studies conducted under CTN / CTX conditions, the TGA must be notified of the new site/s by completion of the appropriate paperwork.

Multi-centre studies

- 4.26. 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.
- 4.27. The reviewing HREC will notify the CPI once HREC approval for the additional sites is granted.
- 4.28. The research must not commence at any additional site until each respective HHS / site has granted authorisation.

Adding the first Victorian site to an approved study

- 4.29. If a research project has already been reviewed and approved, and no Victorian sites were included in the original application, an application to include a Victorian site must be made as an amendment and reviewed by the full HREC.
- 4.30. The amendment application must also be submitted with the *Victorian Module*, which is recommended to have been completed by the PI at the first Victorian site. The Module is submitted with the NEAF to the Reviewing HREC.
- 4.31. The Reviewing HREC will consider this protocol amendment in the usual manner.

Additional Documentation required when Adding a New Site to an Already Approved Project

- 4.32. When adding additional sites to an already approved project, in addition to the requirements outlined above, the following documents must accompany the application:
- the CV of PI at the new sites;
 - Updated CTN form if required;
 - Form of Indemnity – HREC Review Only (commercially sponsored trials only) listing all participating sites for which the HREC has monitoring responsibility; and
 - Certificate of Currency confirming clinical trial insurance.

SECTION 5: Low or Negligible Risk Research Review

- 5.1. *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 ethical review, based on the degree of risk involved. There are three levels of risk:
- Harm;
 - Discomfort; and
 - Inconvenience.
- 5.2. Researchers 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.
- 5.3. Any project that requests a waiver of consent from the individual, for access to identifiable or potentially re-identifiable confidential health information for the purposes of research, must be reviewed by an HREC. *The National Statement* s2.3.5 states that only an HREC can grant a waiver of consent. A subcommittee of an HREC or a LNR committee cannot grant a waiver of consent and a *Public Health Act 2005* application must be made for access to State owned confidential information.

Procedure for Review of Research which is Exempt from a Full HREC Review (Low and Negligible Risk)

All studies

- 5.4. Institutions may establish non-HREC levels of ethical review for low risk research projects. The levels of ethical review may include, but need not be limited to:
- review or assessment at departmental level by the head of department;
 - review or assessment by a departmental committee of peers (with or without external or independent members);
 - delegated review with reporting to an HREC; or
 - review by a subcommittee of an HREC.
- 5.5. 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 LNR review process were assessed as part of the NHMRC Certification process and if the LNR Committee reports directly to the Institutional HREC, then the LNR Committee is able to review multi-centre LNR research projects. The outcome of the LNR Committee must be fully documented in the HREC Agenda and Minutes.
- 5.6. An LNR Committee cannot review multi-centre LNR research if:
- the Institutional LNR review process was not reviewed by the NHMRC at the time of HREC certification;
 - the Institutional LNR review process has been changed since NHMRC certification was granted to the HREC and the NHMRC has not accepted the change; or
 - the LNR committee stands alone and does not advise the HREC of their recommendations.

- 5.7. All LNR research projects must be logged in *AU RED*. Non HREC meetings can be created on *AU RED* in order to allocate LNR studies for review, according to institutional processes. When creating meetings for review of LNR projects, do not use the meeting type *Full* as this term relates to the HREC meetings.
- 5.8. It is the institution's responsibility to determine which level of ethical review process is implemented for LNR research and to create site specific Standard Operating Procedures relating to LNR research review processes.
- 5.9. For all LNR research studies, the LNR form (accessed via the *Online Forms* website) must be completed.
- 5.10. Researchers should be encouraged to contact the local HREC office / RGO to gain an independent assessment of whether the project can be reviewed by a non-HREC process.
- 5.11. If the reviewing panel considers that the application poses more than low risk (even if unlikely), the application will not be eligible to be reviewed by an LNR subcommittee and will be reviewed at a full meeting of the HREC.
- 5.12. A full HREC can review an LNR application form if the risk from participation in the research is no greater than discomfort but where a vulnerable participant group is involved.
- 5.13. If the participation in the research potentially causes more than discomfort a full NEAF must be completed and then submitted for review to an HREC.

Multi-centre LNR studies

- 5.14. All multi-centre LNR applications must be booked through CCS.
- 5.15. All multi-centre LNR applications will be submitted to a certified HREC and will be allocated for review, as appropriate.
- 5.16. On receipt of the notification email from CCS and when the paperwork is delivered to the HREC, the Administrator may allocate the review of the multi-centre LNR project to the LNR committee provided that the provisions of point 5.5 above, have been met.
- 5.17. If the provisions of point 5.5 above have not been met, then the multi-centre LNR study must be reviewed by the full HREC.
- 5.18. Research Governance processes will always need to be completed and submitted to the RGO at each participating site.

SECTION 6: Research Involving Coronial Material

- 6.1. Research involving access to coronial material must be referred to the Queensland Forensic and Scientific Services Human Ethics Committee (FSS-HEC) for ethical and legal approvals. This also applies to clinical research studies where there is a component involving coronial material.
- 6.2. In this context, examples of coronial material include:
 - tissues from coronial autopsies;
 - slides and blocks;
 - blood samples;
 - autopsy reports; and
 - other documents and data relating to coronial autopsies.
- 6.3. The use of material from coronial autopsies for research requires the approval of the State Coroner. If the research involves access to coronial documents, approval as a genuine researcher under s53 of the *Coroners Act 2003* is also required. These approvals are subject to reviews by an ethics committee whose membership includes representatives of the State Coroner.
- 6.4. Fees may be levied by FSS to recover costs associated with ethical review and monitoring of research projects from applicants external to the Queensland Health.
- 6.5. 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.
- 6.6. For further information please refer to *Research Involving Material from Coroners' Autopsies: Advice to ethics committees and researchers* on the Forensic & Scientific Services Human Ethics Committee Site requirements website:
http://www.health.qld.gov.au/ohmr/html/regu/hrec_contacts.asp and
http://www.health.qld.gov.au/ohmr/documents/regu/advice_fss.pdf

SECTION 7: HREC Monitoring of Research Granted Institutional Authorisation

General Guidelines

- 7.1. Research should commence within 12 months of the date of ethical approval.
- 7.2. The 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.
- 7.3. 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 trial should commence.
- 7.4. If the project does not commence within 24 months of the original approval date, the matter should be discussed at a meeting of the HREC. 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.
- 7.5. 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 minuted at the next HREC meeting.
- 7.6. The following people should not be permitted to inspect the HREC files:
 - Sponsor's representatives; or
 - Regulatory authorities.
- 7.7. 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.
- 7.8. 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.

Duration of an Approved Ethical Decision

- 7.9. 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.
- 7.10. The duration of an HREC Approval is individually assessed for each project, taking into consideration the level of risk associated with the study, and based on the Investigator's estimated study duration. Generally, all HREC Approvals are granted for three years (maximum five years), except where action is taken by the Reviewing HREC to suspend or terminate a project.
- 7.11. The duration of the HREC Approval is recorded on *AU RED* under the *Post Approval* tab.
- 7.12. When the end of the HREC Approval period is within three months, a notification will automatically appear on the *AU RED* Work Area to alert the HREC Administrator to follow up the progress of the study with the Investigator.

- 7.13. If an investigator wishes to extend the duration of their HREC Approval, they must request an amendment via a formal letter to the HREC, outlining why and for how long the extension is required.
- 7.14. 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.
- 7.15. 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.

Reporting to the HREC

Commencement report

- 7.16. The HREC Approval letter should provide the researcher with a form for notifying the HREC of the commencement of the study.
- 7.17. The study start date is defined in the Definitions section of this document.
- 7.18. Notification of the study start should be made by the Investigator to the HREC within 30 calendar days of study commencement.
- 7.19. For multi-centre research, the Reviewing HREC is only notified of the commencement date for the first site. The start date for all other participating sites included in the HREC review will be recorded in the Annual Report.

Progress reports

- 7.20. 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.
- 7.21. Reporting time frames should be recorded in *AU RED*.
- 7.22. The Annual Report is due on the anniversary of the date on which ethical approval was given, since this is the only common date for multi-centre research.
- 7.23. Progress reports should be in the format prescribed by the HREC and the location of such report templates be indicated on their website.
- 7.24. Reports must be signed by the by the PI (or CPI for multi-centre studies) before submission.
- 7.25. An HREC may request that investigator-initiated studies are overseen by an independent safety committee, in which case the Committee will specify the reporting requirements in the approval documents.
- 7.26. Progress reports should be added to the agenda and reviewed by the HREC.
- 7.27. Where a progress report is not received by the due date, the HREC Administrator should send a reminder letter. If the report is still not received after a further period of one month, the 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.

Reporting of Urgent Safety Measures

- 7.28. 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.
- 7.29. The HREC and the study Sponsor must be notified immediately that such measures have been taken.
- 7.30. The notice should set out the reasons for the urgent safety measures and the plan for further action.
- 7.31. 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.
- 7.32. 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 or CPI.

Safety Reporting for Clinical Trials

- 7.33. The responsibility of HRECs, and the institutions they advise, is to protect the safety of participants in research.
- 7.34. HRECs have a responsibility to ensure that any risk / benefit changes of study are compatible with ongoing ethical acceptability of the trial.
- 7.35. In order to undertake this responsibility effectively, HRECs must have sufficient reliable information about the implications of adverse events or reactions and the proposed method and timing of safety monitoring, reporting and follow up for a study.
- 7.36. In evaluating the proposed safety reporting processes for a study - as detailed in the Study Protocol - the Reviewing HREC should be satisfied that the processes are commensurate with the risk, size and complexity of the proposed research.
- 7.37. Where the Reviewing HREC determines that it is appropriate, the reporting requirements for a project may be requested more frequently.
- 7.38. A Reviewing HREC should establish with RGOs at the sites for which they have monitoring responsibility, the process and level of institutional monitoring of the project, and the method of providing feedback from the Institution's RGO to the Reviewing HREC.
- 7.39. Individual institutions that agree to allow the conduct of research at their sites must have a documented monitoring procedure in place.
- 7.40. Institutional RGOs must recognise their role in monitoring safety and protocol compliance at a site, and implement a feedback reporting process to the Reviewing HREC.
- 7.41. The DoH endorses two guidance documents for the reporting of adverse events (AEs) and SAEs:
- the NHMRC *Australian Health Ethics Committee (AHEC) Position Statement on the Monitoring and Reporting of Safety in Clinical Trials* (2009),
http://www.nhmrc.gov.au/_files_nhmrc/file/health_ethics/hrecs/reference/090609_nhmrc_position_statement.pdf; and

- the NHMRC *Framework for Monitoring Guidance for the National Approach to Single Ethical Review for Multi-centre Research* (2012), <http://hrep.nhmrc.gov.au/toolbox/guidance-multi-centre-research>

Commercially Sponsored Clinical Trials

Adverse Events

- 7.42. AEs are recorded in the Case Report Form (CRF) for each patient, and are routinely reported to the Study Sponsor by the CRA after each monitoring visit.
- 7.43. AEs are recorded in the safety database periodically during the study (according to the safety plan). Analysis of these results may require an amendment to the Investigator Brochure or Product Information (updated at least annually).
- 7.44. These updates are submitted to the Reviewing HREC.

Serious Adverse Events for Drug Trials

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

2.1 In accordance with individual institutional requirements NB: institutions should seek to keep individual requirements to minimum or utilise such requirements in a highly targeted manner if these are particular safety concerns	<ul style="list-style-type: none"> — to institution (or HREC as specified by institution) — AEs or SAEs occurring at their site(s)
2.2 In a prompt manner to HREC responsible for trial	<ul style="list-style-type: none"> — information which materially impacts the continued ethical acceptability of the trial or — information that requires, or indicates the need for, a change to the trial protocol, including changed safety monitoring in the view of the investigator or sponsor.
2.3 At least six-monthly to HREC responsible for trial	<ul style="list-style-type: none"> — listing of all SUSARs, Australian and international, occurring with a compound — including sponsor and investigator comment as to whether action is planned for the trial on the basis of the reports — EU format is acceptable.

2.4 At least annually to HREC responsible for trial	<ul style="list-style-type: none"> — an updated Investigator Brochure, or — an EU ASR (or similar format report), or — current, approved Product Information (PI), if appropriate (eg in a study for a product approved in Australia or where an Investigator Brochure is no longer maintained) — other reports consistent with section 5.5.5 of the <i>National Statement</i> and Good Clinical Practice (GCP) as adopted by the Therapeutic Goods Administration (TGA).
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- 7.47. SAEs must be reported to the Study Sponsor within 24 hours of the PI becoming aware of the SAE.
- 7.48. The PI must include the site RGO in the notification of the SAE.
- 7.49. SAEs are not reported directly to the HREC by the PI except in the following circumstances:
 - where there is sufficient concern for patient safety that an immediate protocol deviation or amendment is required; or
 - where the incident materially affects the ongoing ethical acceptability of the trial.
- 7.50. It is acceptable for the PI to notify the HREC using the same reporting template that is provided by the Sponsor.
- 7.51. Collations of SAEs occurring during the conduct of a clinical trial are provided by the Sponsor to the CPI, in the form of three or six monthly Line Listings.
- 7.52. The CPI must review the line listings and provide the Line Listings along with their opinion regarding the ongoing safety and ethical acceptability of the study to the HREC.
- 7.53. Updated Investigator Brochures or Product Safety Information must be submitted to the HREC for consideration.
- 7.54. If any changes to the study are required, these must be submitted as an amendment.
- 7.55. All reports, including the cover letter / reporting template, should be uploaded onto the *Online Forms*, by the researcher.
- 7.56. 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.

Serious Adverse Events for Device Trials

- 7.57. Where there is no material impact on the continued ethical acceptability of the Investigation, Unexpected Serious Adverse Device Events (USADEs) are reported as per the trial protocol or HREC Institutional requirements.
- 7.58. USADEs must be reported to the Institution via the RGO in all cases.
- 7.59. USADEs are not reported directly to the HREC by the PI except in the following circumstances:
 - where there is sufficient concern for patient safety that an immediate protocol deviation or amendment is required; or

- where the incident materially affects the ongoing ethical acceptability of the trial.
- 7.60. It is acceptable for the PI to notify the HREC using the same reporting template that is provided by the Sponsor.
- 7.61. Industry Reports or DSMB reports are submitted in a collated format at least annually to the Reviewing HREC. The CPI is required to provide a comment on the collated reports.

Non Commercially Sponsored Trials

- 7.62. The Reviewing HREC is responsible for ensuring that nominated safety review processes for a study are reflective of the level of risk posed by participation in the trial.
- 7.63. Sponsors of non commercially sponsored trials are required to develop adequate safety review mechanisms, such as:
- an Institutional, but independent, Data Safety Monitoring Board (DSMB);
 - a trial management committee;
 - liaison with a pharmacovigilance group (where there is commercial involvement in a study); or
 - other simpler but separate review processes, as agreed by the Reviewing HREC.

Adverse Events

- 7.64. Adverse event reporting should be considered separately from SAE reporting.
- 7.65. Adverse events must be reported regularly to the study Sponsor to enable review and inclusion in the report to their data safety committee for the study.
- 7.66. Adverse events are not reported individually to the Reviewing HREC or Institutional RGO.

Serious Adverse Events

- 7.67. SAEs must be reported to the Study Sponsor within 24 hours of the PI becoming aware of the SAE.
- 7.68. The PI must include the site RGO in the notification of the SAE.
- 7.69. SAEs are not reported directly to the HREC by the PI *except* in the following circumstances:
- where there is sufficient concern for patient safety that an immediate protocol deviation or amendment is required; or
 - where the incident materially affects the ongoing ethical acceptability of the trial.
- 7.70. It is acceptable for the PI to notify the HREC using the same reporting template that is provided by the Sponsor.
- 7.71. For all studies the Investigator must include an assessment of the event, along with notification of any amendments that have been determined for the study. The notification to the HREC must also include the report from the DSMB.
- 7.72. Where the CPI is not the sponsor of the study, SAEs must be reported to the study Sponsor within 24 hours of the PI becoming aware of the SAE.
- 7.73. The Sponsor or CPI must provide evidence to the Reviewing HREC of communications to all participating sites, notifying them of the safety issue.

- 7.74. The Reviewing HREC must be satisfied that appropriate reporting of the event to the TGA has been undertaken by the Sponsor.
- 7.75. Where changes to the study are required, these must be submitted as an amendment to the HREC.
- 7.76. All reports, including the cover letter / reporting template, should be uploaded onto the *Online Forms* web site by the researcher.
- 7.77. An annual trial update that summarises all safety information about the project must be compiled by the DSMB for the project, and submitted to the Reviewing HREC. This summary must also indicate where amendments to the protocol have been required due to safety issues.

Summary of Reporting of Serious Adverse Events

- 7.78. SAEs occurring at a site must be reported to the study Sponsor and the site RGO within 24 hours of the PI becoming aware of the SAE.
- 7.79. SAEs are only reported to the Reviewing HREC when there is sufficient concern for patient safety that an immediate protocol deviation or amendment is required, or where the incident materially affects the ongoing ethical acceptability of the trial.
- 7.80. The study Sponsor is responsible for notifying the TGA of individual SAEs.
- 7.81. Participating sites must have a mechanism for the review of SAEs occurring at their Institution, which is external to and separate from the HREC.
- 7.82. The Institution's safety review committee will make a determination as to whether or not the study may continue at the site.
- 7.83. All decisions from institutional safety review bodies must be communicated back to the study sponsor.
- 7.84. For commercially sponsored trials, the study sponsor must provide the Reviewing HREC with three or six monthly line listings, detailing all SAE occurring since the last reporting period. The Sponsor must also provide an annual safety update or updated Investigator Brochure.
- 7.85. For non-commercially sponsored trials, an annual safety report (or more frequently, if requested by the Reviewing HREC) with a collation of all safety events and actions taken, including protocol amendments, must be provided to the Reviewing HREC and all participating sites.
- 7.86. Where any SAE results in a change to the study protocol, this change must be submitted as a protocol amendment and processed in the usual way.

Tracking of Medical Devices

- 7.87. Tracking of medical devices is undertaken as per the TGA requirements and Australian Medical Devices Guidelines.
- 7.88. To access the TGA guidelines use this link:
 - <http://www.tga.gov.au/industry/clinical-trials-guidelines.htm>
 - <http://www.tga.gov.au/industry/clinical-trials-handbook.htm>
- 7.89. To access the Australian Regulatory Guidelines for Medical Device, use this link:
 - <http://www.tga.gov.au/industry/devices-argmd.htm>

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

Protocol Deviations and Violation

- 7.91. The distinction between protocol violations and protocol deviations is neither clearly understood nor consistently applied amongst Australian HRECs.
- 7.92. 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.
- 7.93. Protocol Violations require retrospective notification to or review by an HREC.
- 7.94. Protocol Deviations relate to other matters and will require notification to or review by an HREC.
- 7.95. These definitions are consistent with ICH/GCP taxonomy. (Source: *NHMRC Framework for Monitoring: Guidance for the national approach to single ethical review of multi-centre research*).
- 7.96. The PI is responsible for reporting protocol deviations or violations to the HREC.
- 7.97. Deviations / violations should be noted at the next HREC meeting.
- 7.98. The HREC should determine whether there is cause to consider if research misconduct has taken place. Follow up action is at the discretion of the HREC.

Reporting Early Termination of a Study by the PI

- 7.99. Notification of early termination of a study should be added to the agenda and reviewed by the full HREC.
- 7.100. The study status on *AU RED* should be updated to *Terminated*.
- 7.101. If the Investigator has not uploaded the study documentation against their initial application, the documentation should be scanned and uploaded in to the History of the study by the HREC Administrator.

Suspension of HREC Approval

- 7.102. The HREC may suspend its ethical 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 ethical approval and that, as a result, the welfare and rights of participants are not or will not be protected.
- 7.103. Where the HREC considers it appropriate that the adverse event/s and / or monitoring report requires the immediate suspension or discontinuation of the ethical approval of the research project, the HREC should immediately notify the CPI (or Site PI for single site studies) and instruct them to:
- Immediately cease all study related activities;
 - ensure the health and wellbeing of participants is not compromised;
 - notify any study sponsor of the HREC's decision; and
 - notify their RGO and HHS CE.

Suspension or Withdrawal of Research Authorisation by the HHS /Site Research Governance Office/rs

- 7.104. Where the Queensland DoH HHS CE or delegate is satisfied that circumstances have arisen such that it is no longer appropriate to conduct the research study at the site, the HHS may suspend or withdraw its authorisation to conduct the research at the site.
- 7.105. If the HHS CE or delegate suspends or withdraws authorisation the researcher must within three working days:
- Immediately cease all study related activities;
 - ensure the health and wellbeing of participants is not compromised;
 - notify any study sponsor of the CE's decision;
 - notify the HREC; and
 - notify the CPI (if the study is multi-centre).
- 7.106. Where there is suspension or withdrawal of research authorisation by the HHS / Site RGO, the HHS CE or delegate should consult with the HREC to consider any safety aspects for research participants that may be involved in the study at the time of suspension or withdrawal of HHS authorisation.
- 7.107. The HREC Administrator should log the study in *AU RED*, in the *Post Approval* tab, as being Suspended or Halted Temporarily as the case may be. Additional notes may be recorded in the *Note* facility attached to *Study Status* section.

Final Reports

- 7.108. The HREC should receive notification from the CPI / PI that a study is finished. This means that recruitment is closed, all participants have completed the study, all data has been submitted to the Sponsor and all data queries have been resolved. In this case, the HREC Administrator will mark the study, on *AU RED*, as *Finished*.
- 7.109. A final report on all research given ethics approval should be submitted to the HREC within 30 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.
- 7.110. Final reports should be added to the agenda and reviewed by the committee. The study status should be updated in *AU RED* to *Closed* and *Archived*.
- 7.111. 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.

Closure of a Study on *AU RED*

- 7.112. There are several options available to the HREC Administrator when closing a study on *AU RED*.
- 7.113. *Abandoned* is used when a researcher is unable to be contacted and the RGO at the research site does not have a record of the study having been started. Alternatively the researcher may be started the study but not progressed it all.

- 7.114. *Finished* is the term used when active work on the study at the site is completed e.g. no further recruitment or data collection is being undertaken. The study is not marked as *Closed* as the Final Report may not have been completed at this time.
- 7.115. *Terminated* is used if the study is closed prematurely for any reason. The reason for the early closure can be recorded in the *Notes* facility.
- 7.116. *Closed and Archived* is the option used when the Final Report has been sent in, acknowledgement has been sent to the researcher from the HREC and all study documents are filed and prepared for archiving.

SECTION 8: Archiving, Storage and Retention of HREC Records and Documentation

General Information for all HREC records

- 8.1 The Queensland DoH Strategic Records Management Team have advised that until such time that the retention disposal schedule has been approved by Queensland State Archives all HREC records should be held by sites indefinitely.
- 8.2 These records may be hard copies or in electronic format.
- 8.3 Further information can be obtained from the Queensland DoH Strategic Records Management Team on 3239 0928.

Archiving completed studies

- 8.4 Once a study has been completed and logged in *AU RED* as being *Completed and Archived*, the project and all accompanying documentation may be removed from the HREC Office and archived.
- 8.5 Research projects should be archived according to the year the study is completed.
- 8.6 Within each archive box, projects should be stored in numeric order according to the year they were approved.
- 8.7 A record of the archive box identifier is entered with in *AU RED*, on the *References* page for the study, in the *Archive Number* field.

SECTION 9: Fees for HREC Review of Research Applications

General Guidance

- 9.1 The Australian Health Ethics Committee (AHEC) - <http://www.nhmrc.gov.au/about/committees-nhmrc/australian-health-ethics-committee-ahec> - acknowledges the need of institutions to defray the costs of adequately resourcing an HREC, whilst outlining ethical issues and potential concerns associated with the charging of fees by institutions for the ethical review of a study.
- 9.2 AHEC recommends that organisations consider the following ethical issues prior to implementation of fees:
- the potential for the policy to compromise the integrity of ethical review of research applications;
 - the potential for loss of independence and autonomy of HRECs; and
 - the potential to prevent ethical consideration of research applications due to inability to pay, e.g. students.
- 9.3 Queensland DoH, whilst acknowledging these concerns, has implemented a policy of charging fees for commercially sponsored research projects for:
- HREC review;
 - independent expert review and
 - site-specific assessments of research applications (unless exempt).
- 9.4 Queensland Health HRECs should apply these fees consistently throughout the state.

Schedule of Fees

- 9.5 Review of new applications and substantial amendments by the HREC may be subject to a fee: http://www.health.qld.gov.au/ohmr/documents/fees_spnsrd_rsrch.pdf

Payment of Fees

- 9.6 It is the responsibility of the researcher to provide the HREC / finance office with details of the sponsor organisation contact to whom the invoice will be sent.
- 9.7 Institutions may elect for invoices to be paid prior to dispatch of approval letters.
- 9.8 If cheques are received by the HREC, they should be promptly forwarded to the Finance Department in line with local administrative requirements and recorded on *AU RED*.

Exemptions from Fees

- 9.9 The Queensland DoH Research Management Policy (Research Governance Implementation Standard) exempts all non-commercial research projects from any review fees. http://www.health.qld.gov.au/ohmr/html/regu/resrch_mge_policy.asp

What does the Fee for Ethical Consideration by a Queensland Health HREC cover?

9.10 The Queensland DoH HREC Fees enable HREC Administrators and Members to fulfil their duties and support activities such as:

- 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;
- liaising with other sites and reporting to AHEC, HHS Boards and Queensland Department of Health as part of their Service Level Agreements;
- payments to external expert reviewers and others as necessary;
- advising and providing ethical education and training to researchers and HHS HREC members and Administrators;
- maintaining the Queensland Department of Health Research Ethics Database (*AU RED*);
- liaising between the HREC and researchers regarding submissions, requests for clarification, responses, exempt and low risk review and incomplete applications;
- providing advice and assistance to researchers in the submission of research applications;
- liaising with other HREC Administrators regarding the status of submission of multi-centre research applications;
- training of HREC members and administrators. This includes forwarding NHMRC announcements, notices of upcoming educational activities, arranging registration, travel and accommodation to conferences for HREC members;
- monitoring of approved research studies, requesting reports, locating and contacting noncompliant researchers, invitations to researchers to address the committee;
- compliance with legislation and guidelines, keeping the Committee informed of the most recent developments surrounding topical issues;
- invoicing sponsors for HREC fees, receipting, reconciliation, follow up of unpaid invoices;
- facilitating and participating in meetings of the HREC Administrators. This group consists of Administrators from public and private hospital HRECs in Queensland. The group's focus is to disseminate information, to 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; and
- meeting the costs of meetings and travel expenses of committee members.

SECTION 10: Management of an HREC

Process for Appointing HREC Members

- 10.1 The *National Statement* s5.1.34 provides guidance on recruitment of HREC members.
- 10.2 The institution is to recruit members for an HREC using open and transparent processes.
- 10.3 Advertisements may be placed, seeking members for an HREC, or potential members may be referred to the Committee.
- 10.4 Normal background checks, as applicable to the Institution will be undertaken, for applicants external to the Institution
- 10.5 Membership must reflect *The National Statement* minimum membership requirements as listed in s5.1.29. Members are to be appointed for their expertise and knowledge and not in a representative capacity of any organization, group or opinion.
- 10.6 Members are not to be appointed in more than one of the categories listed in s5.1.30 of *The National Statement*.
- 10.7 An HREC may establish a pool of inducted members in each category.
- 10.8 Institutions should review appointments to the HREC at least every three years.
- 10.9 Appointed members must receive a formal notice 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 committee members.
- 10.10 Members should undertake appropriate induction. This includes providing a copy of *The National Statement*, *The Code*, HREC Terms of Reference and HREC meeting dates.
- 10.11 The minimum membership for an HREC meeting is 8 members. However, it is advised that the HREC is compromised of at least 12-15 members to account for absences and to provide the Committee with a wide range of professional backgrounds
- 10.12 Induction should also include mentoring by a current HREC member and continuing education (refer to Section 11.21 Education and Training for HREC Members and Administrators).
- 10.13 Membership of the HREC, which does not include actual members names, should be made available to the public via an annual report or by other routine processes, such as to researchers submitting research proposals to the HREC.

Reimbursement of Expenses for HREC Members

- 10.14 It is the responsibility of the HREC Administrator to ensure that HREC members' legitimate expenses are reimbursed without delay.
- 10.15 Reasonable expenses incurred travelling to and from HREC meetings will be reimbursed.
- 10.16 The original receipt is required.
- 10.17 Complete Petty Cash Voucher.
- 10.18 Complete Staff Expense Claim.

Education and Training

- 10.19 Training and education on ethical review should occur at least every second year.
- 10.20 Members and staff wishing to attend should complete an Application for Conference and Study Leave.
- 10.21 The local HREC Administrator will oversee all applications, i.e. approval by authorised persons, travel arrangements through the Travel Hub and payment through Finance Department.
- 10.22 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.
- 10.23 It is the responsibility of the Administrator to maintain a register of all training provided to committee members.

Essential Reading for HREC Members

- *National Statement on Ethical Conduct in Human Research* (2007). NHMRC
- *Australian Code for the Responsible Conduct of Research* (2007), NHMRC and Universities Australia
- *Therapeutic Goods Administration Note for Guidance on Good Clinical Practice* (CPMP/ICH/135/95) (2000)
- *Public Health Act 2005* (part 4, Division 2 s281)
- Guidelines under Section 95 and 95a of the *Privacy Act 2009*
- *Information Privacy Act 2009*
- Queensland Department of Health Research Management Policy December 2012 or any subsequent revised policy document.
- Financial Standard 1997
- *Coroners Act 2003*, s53
- Code of Conduct for the Queensland Public Service
- *Values and Ethics – Guidelines for Ethical Conduct in Aboriginal and Torres Strait Islander Health Research* (2003) NHMRC

Certification with the NHMRC

- 10.24 As part of the preparations for the National Approach, the NHMRC introduced a certification process for those HRECs who wished to nominate themselves to undertake single ethical review of multi-centre research.
- 10.25 The National Certification Scheme is voluntary. Certification provides assurance that the policies, processes and procedures of the Institution and its HREC comply with an agreed set of national criteria for the conduct of an ethical review of multi-centre human research.
- 10.26 The following link to the NHMRC website provides information on applying for certification or re-certification. <http://www.hrep.nhmrc.gov.au/certification/nomination-certification>

- 10.27 Assessment for certification or re-certification consists of a self assessment questionnaire completed by the HREC, then a desk top audit by the NHMRC assessors, and finally a site visit by the NHMRC assessors.
- 10.28 Initial certification is for three years, but can be temporarily or permanently suspended by the NHMRC.
- 10.29 Reasons for suspension of certification include:
- failure by the institution via its HREC to meet its reporting obligations to the NHMRC;
 - failure by the institution to ensure that the HREC maintains the appropriate level of specialist knowledge for any nominated research categories;
 - failure to appropriately monitor multi-centre research in accordance with any NHMRC guidelines on monitoring multi-centre research or other relevant national or local guidelines;
 - failure by the institution to maintain the appropriate level of insurance for its HREC;
 - repeated, unreasonable refusals by the certified institution to accept the ethics review of another certified institution;
 - an unreasonable refusal by the certified institution to undertake a review of an application for single ethical review of multi-centre research;
 - failure by the HREC or certified institution to comply with the requirements of the *National Statement*, the *Code for the Responsible Conduct of Research* (2007) or any other guidance document issued by the NHMRC relating to the ethical or responsible conduct of human research;
 - failure to provide requested information to the NHMRC for the purposes of assessing whether the institution continues to meet the assessment criteria;
 - accepting an application for single ethical review of multi-centre research in a suspended research category subject to a partial suspension;
 - accepting an application for single ethical review of multi-centre research during a period of voluntary suspension;
 - representing that the institution is certified to review multi-centre research in a category of research for which it is not certified;
 - failure by the institution to accept a valid application for ethical review of a multi-centre human research project submitted on the NEAF; or
 - engaging in conduct which otherwise places participants, researchers and the public at risk or jeopardises the reputation of the National Certification Scheme.
- 10.30 Applications for re-certification must be made prior to the current certification expiring.
- 10.31 Failure of an institution to attain renewal of certification prior to the expiry of their current period of certification will mean that an institution will no longer be certified and will be removed from the register of certified institutions. The institution must also remove its certification certificate from public display and ensure that any correspondence and/or information on institutional practices are updated to remove references that it is a certified institution.

SECTION 11: Handling Complaints

General Guidance

- 11.1 Research complaints can be about the conduct of research including the conduct of the researchers, and / or about the conduct of the HREC.
- 11.2 *The Code* includes a description of research misconduct and includes processes for institutions to handle these complaints.
- 11.3 Handling of research complaints including misconduct is the responsibility of the Reviewing HREC's institution.

Complaints concerning the Conduct of a Project

- 11.4 As per *The Code*, an institution will:
 - nominate advisers in research integrity to counsel complainants about research conduct issues and explain the options open to persons considering making, or having made an allegation; and
 - nominate a designated person for handling research complaints, including research misconduct.
- 11.5 Any concern, allegations or complaints about the conduct of a project must be reported, in the first instance, to the Reviewing HREC, and the institution's designated person for handling research complaints, including research misconduct.
- 11.6 Any complaints received must also be forwarded to the HREC Administrator of the Reviewing HREC who will enter the complaint details on *AU RED* and to the local site RGO where the complaint applies.
- 11.7 Initially, complaints should be forwarded by the designated person to the relevant department to be dealt with at departmental level.
- 11.8 The departmental decision will be reported back to the designated person and the HREC Administrator.
- 11.9 The designated person will review the departmental decision and make a recommendation to the HREC on the appropriate course of action.
- 11.10 If the complainant is not satisfied with the outcome of the designated person's investigation, then he / she can refer the complaint to the institution's CE or his / her delegate for appeal.
- 11.11 For allegations not resolved at a departmental level or through appeals, the Institution's CE or his / her delegate will establish an investigating committee; nominating three independent individuals, who do not have any conflict of interest in the case and have appropriate expertise to evaluate the research issues, to review the case.
- 11.12 The decision of the investigating committee will be final.
- 11.13 Participant Information Sheet and Consent forms must include contact details to allow such complaints to be made.

- 11.14 All complaints will be acknowledged within seven days by the Institutional Representative to whom the written complaint was submitted.
- 11.15 The complainant will be advised of the decision within 30 days by the HREC Administrator.

Complaints concerning the HRECs Review Process including the HRECs Rejection of an Application

- 11.16 Any concern or complaint about the HREC's review process should be directed to the attention of the Chair of the HREC, detailing the concern in writing.
- 11.17 The Chair will notify the HHS CE of any complaints received, as soon as possible. Similarly, the HHS CE will inform the Chair of any complaints received by as soon as possible.
- 11.18 The Chair will investigate the complaint and its validity, and make a recommendation to the Reviewing HREC on the appropriate course of action.
- 11.19 If the complainant is not satisfied with the outcome of the Chair's investigation, then he / she can refer the complaint to the CE, or his / her nominee, or request the Chair to do so.
- 11.20 The Chair will provide to the CE all relevant information about the complaint / concern.
- 11.21 The CE will determine whether there is to be a further investigation of the complaint.
- 11.22 If it is decided there is to be a further investigation, then the CE will convene an investigating committee to review the complaint, ensuring that both the complainant and the HREC are afforded the opportunity to make submissions. I
- 11.23 In conducting its review, the panel shall be concerned with ascertaining whether the HREC acted in accordance with *The National Statement*, its Terms of Reference, the Standard Operating Procedures, or otherwise acted in an unfair or unbiased manner.
- 11.24 The decision of the investigating committee will be final.

Appendix 1

Multi-Centre v Single Centre – Guidance for Queensland Health HREC Administrators

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

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

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

HREC Administrators Checklist

to be completed prior to uploading a new project into AURED

Relevant sections of the NEAF to assist with determining whether a Study is a Multi-centre Research Project	
Section 1	Study Title
Q 1 (LNR 2.1)	Does the title include the words "Multi-centre", "Multi site", "State wide", "National' or "International":
Section 2 (LNR 1.1)	Researchers and Investigators
Q 2.2 (LNR 2.2)	Are there other Principal Investigators listed, who are not from your site? Relevant box for multicentre or single centre should be checked
Section 3	Sponsor
Q 3.1(c)	If the study is sponsored by Industry or a major Collaborative Funder (e.g. NHMRC) or Research Group (eg ALLG) it is likely to be a multi-centre study. Please contact the researcher if you are still unsure.
Section 4	Prior Reviews (LNR Section 3)
Q 4.1 (LNR 4.1)	Other Australian sites or site types participating in the research study should be listed here.
Q 4.2	The number of participating international sites will be listed here.
Q 4.3	Details of other participating Australian sites will be listed here.
Q 4.6 (LNR 3.1)	The details of other Australian HRECs to which the study has been submitted will be listed.

If the research project you have just received is deemed to be a multi-centre research project, and if you have not received notification on your *AU RED* Work Area from CCS about this study, do NOT proceed to check it in. Please tell the researcher to contact CCS on 1300 753 227.

Checklist for All Research Projects

Mandatory components for all submissions to a HREC, including Low & Negligible Risk Projects.		
1	Cover letter, with brief description of project, signed by the Coordinating Principal Investigator. In addition, the letter must contain the following information: <ul style="list-style-type: none"> • For commercially sponsored studies, the name and address of the Sponsor organisation / CRO must be included to allow for billing for the HREC review. • A list of all participating sites for which HREC review is requested • If multi-centre booked via the CCS please add the allocated HREC Reference Number. • A list of all supporting documentation submitted with the HREC application 	
2	For Low and Negligible Risk (LNR) studies, a completed and signed LNR Application Form, and all supporting documentation.	
3	For all other studies, a completed and signed NEAF with "Submission Code" and all supporting documentation.	
4	Study Protocol. The NEAF or LNR is not a study protocol.	
5	CVs for researchers who have not submitted a CV within two years.	
6	Form of Indemnity – HREC ONLY – must be provided with the NEAF or industry sponsored clinical trials: http://medicinesaustralia.com.au/files/2010/09/Form-of-Indemnity-HREC-Only-version-230507B.doc	
7	If a multi-centre study, a copy of the Central Coordinating Service Notification email	

NB: Please remember to complete the *Details* tab of *AU RED*, with regard to Student Researchers, Low and Negligible Risk Research, and Private Sector.

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