



Standard Operating Procedures (SOP) for QH HREC Administrators

Office of Health and Medical Research

Queensland Health

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These Standard Operating Procedures have been developed in the Research Ethics and Governance Unit of the Office of Health and Medical Research with valuable input and contributions from Queensland Health Human Research Ethics Committee (HREC) Chairs, administrative staff and members.

INTRODUCTION

Purpose and scope

The Standard Operating Procedures (SOPs) in this document meet the guidelines contained in 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 QH Research Management Policy (QHRMP; 2010).

These SOPs apply to the conduct of all research involving human participants carried out within or in association with Queensland Health (QH) facilities, patients, staff, data, records or information.

Implementation

All QH HRECs are required to operate in accordance with these SOPs with effect from 1 July 2010.

HRECs may develop additional local operating procedures to deal with local matters not addressed in these SOPs or within permitted discretion.

All research proposals for ethical review are to be submitted using the National Ethics Application Form accessed via <http://www.ethicsform.org>.

HRECs will direct researchers to upload all supporting documentation onto the online forms NEAF website.

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-scientific review of the 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 single ethical review process.

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

Australian Research Ethics Database (AU RED)

The electronic application tracking and management system, the Australian Research Ethics Database (AU RED) will be used to underpin the operation of the system, allowing the timely communication of reviews between investigators, the authorising HRECs and sites. It will also measure the performance of the new system and that of individual HRECs and the Central Coordinating Service in relation to such matters as efficiency and timeliness.

HRECs are required to use the standard letter (SL) templates and standard forms (SF) templates as generated by AU – RED and as listed in Annex A where indicated in the SOPs. The standard letters generated by AU-RED can be downloaded into MS Word for modification where necessary. Throughout the SOPs standard letters and forms generated by AU-RED are marked with **AU-RED ALERT**.

DEFINITIONS AND APPREVIATIONS

Adverse event	<p>Any untoward medical occurrence in a patient or clinical investigation subject administered a pharmaceutical product and which does not necessarily have a causal relationship with this treatment.</p> <p>An adverse event (AE) can therefore 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>
Applicant	For multi centre studies the Coordinating Principal Investigator. For single site studies the Site Principal Investigator.
AuRED	A secure web-based Research Ethics Database that allows researchers to complete and submit a NEAF application online.
Central Coordinating Service (CCS)	The Central Coordinating Service (CCS) provides a “one stop shop” information service for the processing of multi-centre research applications within Queensland Health sites. Use of the Central Coordinating Service for multi-centre research in Qld Health sites is mandatory from 1 July 2010. Please note that this will be displayed on AU-RED as CAS.
Coordinating Principal Researcher	The investigator responsible for coordinating a research study. For single centred studies the terms “Coordinating Principal Investigator”, “Coordinating Principal Researcher”, “site Principal Investigator” and “Principal Investigator” are all synonymous.
Clinical Research Coordinator	The person designated by the Principal Investigator (PI) to be responsible for liaising with the HREC / research governance office(r). May also be known as the site coordinator, contact person, study liaison officer.
Contact person	The person designated by the PI to be responsible for liaising with the HREC / research governance office(r). May also be known as the site coordinator, clinical research coordinator, study liaison officer.
CPI	Coordinating Principal Investigator. The investigator responsible for coordinating a multi-centre research study,

and the submission and communication of all subsequent requests and notifications to the site Principal Investigators. For single centred studies the terms “Coordinating Principal Investigator”, “Coordinating Principal Researcher”, “site Principal Investigator” and “Principal Investigator” are all synonymous.

HREC Coordinator	An employee of the institution who provides administrative support and advice on the institution’s process of ethics review of research studies. The coordinator reports to the Chair of the HREC in matters related to the activities of the Committee. The terms “HREC administrator”, “HREC coordinator” and “HREC secretariat” are all synonymous.
Low risk research	Section 2.1.6 of the National Statement on Ethical Conduct in Human Research describes research as “Low Risk” where the only foreseeable risk is one of discomfort. Where the risk, even if unlikely, is more serious than discomfort, the research is not low risk.
Minor amendment	An amendment not requiring review by a full HREC. Can receive approval outside of scheduled HREC meeting. Changes to the details of research that have no significant implications for subjects or for the conduct, management or scientific value of the study and can be regarded as minor amendments (sometimes referred to as “administrative amendments”). Examples as follows: <ul style="list-style-type: none">• Correction of typographical errors in the protocol or other study documentation• Amended contact details for the sponsor or study staff• Appointment of new support staff
MCR	Multi-centre Research. Research to be conducted at more than one site (this may include sites other than Qld Health sites) and within the jurisdiction of more than one HREC. For applications via the CCS the research study must be conducted at more than one centre across HREC jurisdictions, and under the old system would have required submission to more than one HREC
Negligible risk research	Section 2.1.7 of the National Statement describes research as “negligible risk” where there is no foreseeable risk of harm or discomfort; and any foreseeable risk is not more than inconvenience. Where the risk, even if unlikely, is more than inconvenience, the research is not negligible risk.”
Principal Investigator	An investigator who acts as Principal Investigator at a study site i.e. the investigator responsible for the overall conduct of

the research study at an individual site within a Health Service District of QH. For single centred studies the terms “Coordinating Principal Investigator”, “Coordinating Principal Researcher”, “site Principal Investigator” and “Principal Investigator” are all synonymous.

Quality Assurance	<p>An activity where the primary purpose is to monitor, evaluate or improve the quality of health care delivered by a health care provider (an individual, a service or an organisation) is a quality assurance study. Attempts to clearly separate quality assurance from research are difficult. What really matters is that:</p> <ul style="list-style-type: none">(a) quality assurance is undertaken for a valid purpose and its outcomes are used to improve health care;(b) those who undertake quality assurance adhere to relevant ethical principles and State, Territory and Commonwealth legislation; and(c) where quality assurance proposals could infringe ethical principles that guide human research, independent ethical scrutiny of such proposals should be sought.
REGU	Research Ethics and Governance Unit.
Research Authorisation	Authorisation issued by the QH HSD District CEO or delegate to conduct research at the Health Service District/Site. Authorisation is contingent upon receiving HREC approval and a completed site-specific assessment.
RGO	<p>Research Governance Office(r) / Function</p> <p>The Office or coordinated function within an institution / district which is responsible for assessing the site-specific aspects of research applications, make a recommendation to the District CEO / delegate as to whether a research study should be granted authorisation at that site, and overseeing that authorised research at the site meets appropriate standards (research governance).</p>
Single-site research	Research to be conducted at one site only within the QLD public health system. If only one SSA needs to be generated the research is single site research.
Site Principal Investigator	An investigator who acts as Principal Investigator at a study site in a multi-centre research study i.e. the investigator responsible for the overall conduct of the research study at an individual site within a Health Service District of QH. For single centred studies the terms “Coordinating Principal Investigator”, “Coordinating Principal Researcher”, “Site Principal Investigator” and “Principal Investigator” are all

synonymous.

Site-specific Amendment	An amendment request for an authorised research study that may be submitted by the applicant to the site/District Research Governance Office/r only (by-passing the HREC).
Site coordinator	The person designated by the PI to be responsible for liaising with the HREC/District/Site research governance personnel. The terms “contact person”, “clinical research coordinator”, “site coordinator” and “study liaison officer” are all synonymous.
60-day clock	The period of 60 days allowed for the issue 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.
SSA	Site Specific Assessment The mechanism used by health service facilities within Queensland Health, to document the level of support and suitability of a research study to be conducted at a site, whether that study is multi-centre or single-site.
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. 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 District/Site RGO for further information or clarification.
Study liaison officer	The person designated by the PI to be responsible for liaising with the HREC / District/site research governance personnel. The terms “contact person”, “clinical research coordinator”, “site coordinator” and “study liaison officer” are all synonymous.
Substantial amendment	An amendment to the terms of the HREC application, or to the protocol or any other supporting documentation, that is likely to affect to a significant degree: <ul style="list-style-type: none">• the safety or physical or mental integrity of the subjects of the trial• the scientific value of the trial• the conduct or management of the trial

- the quality or safety of any investigational medicinal product used in the trial.

25 day clock	The period of 25 days allowed for the SSA decision by the District CEO or delegate of a research application. The clock starts on receipt of a valid SSA.
Validation	An administrative check carried out by an HREC or RGO Administrator to verify that an application is complete and accepted for review. Decisions on validation should be made within one week of receipt.
Validation date	<p>For research not requiring review at a full HREC meeting, the date on which a valid application is received by a HREC.</p> <p>For research requiring review at a full HREC meeting, the relevant HREC meeting closing date</p> <p>For research governance: the date on which a valid application is received by a RGO.</p>

SECTION 1: NEW APPLICATIONS FOR ETHICAL REVIEW

Submission of Research Applications

All Studies

- 1.1 All new applications for ethical review are to be submitted using the online forms National Ethics Application Form (QH NEAF) accessed via <http://www.ethicsform.org>.
- 1.2 In the case of student research, if the student's primary supervisor is not a Queensland Health employee, this supervisor, should nominate a Queensland Health educational supervisor/Student Liaison Officer. This person may also be the Project Liaison Officer. All correspondence will be addressed to the Site Principal Investigator (single site studies) or the Coordinating Principal Investigator (multi-centre studies) , with copies of all correspondence being sent to the educational supervisor/Student Liaison Officer.

Queensland Health Internet Student Orientation Package Checklist (SF29).

- 1.3 If the application and supporting documentation has not been uploaded via the online website portal the HREC administrator should request that the researcher electronically uploads the application and supporting documentation. This ensures that all data is automatically uploaded into AU-RED.
- 1.4 To be included in the next HREC meeting agenda all applications are required to be received by the local HREC office by the last date for submission.
- 1.5 Applications must be accompanied by a completed SF1: 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).
- 1.6 Photocopying and collating the required number of copies of documents is the responsibility of the applicant.
- 1.7 A list of Meeting Dates will be made available by the HREC office to prospective researchers and the Research Ethics and Governance Unit, Office of Health and Medical Research, by 31 October of the preceding year.

Single Site Studies

- 1.8 An application for ethical review of a research study is made by the Site Principal Investigator directly to the applicable HREC.

- 1.9 Applications are not submitted by the sponsor(s) on behalf of the Site Principal Investigator.
- 1.10 A Site Principal Investigator may nominate a study coordinator through which the HREC may communicate.
- 1.11 In the case of research projects with separate protocols governing one or more sub-studies in addition to the main study, a full application should be submitted for each protocol. Similarly, extension studies should in most cases be submitted as separate protocols.

Multi-centre Studies

- 1.12 All studies will have a Coordinating Principal Investigator (CPI) for the project.
- 1.13 The Coordinating Principal Investigator may nominate a Study Coordinator through which the reviewing HREC may communicate.
- 1.14 Applications are not submitted by the sponsor(s) on behalf of the Coordinating Principal Investigator.
- 1.15 Submission of a multi-centre research project for review by a certified HREC will be through the use of the QH Central Coordinating Service (CCS)
- 1.16 Once the HREC has received notification of the application from the CCS, on AU RED, the HREC administrator can commence the process of ethical and scientific review.
- 1.17 For multi-centre research studies, submitted under the single ethical review process, a designated HREC which has had its HREC processes assessed and certified under the national certification scheme will be the single HREC body to conduct the ethical-scientific review of the 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 single ethical review process

Extension of a research study to an additional site

Single site studies

- 1.18 Where a single site study is to be extended to additional site/s, the local PI will take on the role of the CPI.
- 1.19 If the original approving HREC is not certified to approve multi-centre research in the study field, the CPI will be required to submit the study to a certified HREC for approval. The CPI will be required to contact the Central Coordinating Service at QH REGU to determine which HREC will review the application.

- 1.20 If the original approving HREC is certified to approve multi-centre research in the study field, and originally approved the study after 1 July 2010, the CPI will submit an amendment to the original approving HREC.
- 1.21 In all cases, for studies approved prior to 1 July 2010, the study will need to be submitted through the Central Coordinating Service for allocation to a suitable HREC (this is to ensure that the original reviewing HREC is certified in the study field to approve the research study)
- 1.22 The approving HREC will notify the CPI once HREC approval is granted.
- 1.23 The CPI will notify the local PI who will then apply to the local RGO for district authorisation.
- 1.24 The research will not be able to commence at each additional site until each respective district/ site has granted authorisation.
- 1.25 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

- 1.26 If the original approving HREC is not certified to approve multi-centre research in the study field, the CPI will be required to submit the study to a certified HREC for approval. The CPI will be required to contact the Central Coordinating Service at QH REGU to determine which HREC will review the application.
- 1.27 Where a multi-centre study has been approved by a certified HREC in the study field and originally approved the study after 1 July 2010, and is to be extended to include additional site/s, the CPI will apply for approval from the approving HREC for the addition. This ensures that the approving HREC has the relevant information to correctly monitor the study.
- 1.28 For studies approved prior to 1 July 2010, the study will need to be submitted through the Central Coordinating Service for allocation to a suitable HREC (this is to ensure that the original reviewing HREC is certified in the study field to approve the research study)
- 1.29 The reviewing HREC will notify the CPI once HREC approval is granted.
- 1.30 The CPI will notify the local PI who will then apply to the local RGO for district authorisation.
- 1.31 The research will not be able to commence at each additional site until each respective district/ site has granted authorisation.

Uploading Applications to AU RED

Single Site Studies

- 1.32 Following registration of an application on AU RED, a unique identifying number will be generated by the AU-RED database.
- 1.33 NEAF applications created on a NHMRC NEAF will need to be converted by the researcher to an online NEAF, accessed via <http://www.ethicsform.org>. Refer the researcher to the Researcher User Guide for details on converting the NEAF.
- 1.34 To upload an online NEAF, click on the 'Upload online form data' button on the 'Details' page of the application on AU RED and enter the 'Submission Code' on the bottom right hand side of the NEAF application.
- 1.35 If there is no 'submission code' on the NEAF you will need to contact the researcher and ask them to 'create a submission code' their NEAF and inform you of the 'submission' code.
- 1.36 All researchers must electronically 'upload' all supporting documentation (eg participant information sheets, investigator brochures, protocol etc) through the online NEAF site. This ensures that the HREC administrator receives and has a record of all the supporting documentation sent. Names, dates and version numbers of uploaded documents will also be automatically populated into the HREC approval letter.

Multi-centre Studies

- 1.37 An automatically generated email will be sent from the CCS (CAS) to the caller and CPI (cc'd to the HREC Coordinator), informing them of all the required information, including the HREC to which their application has been allocated for review. AU RED will automatically generate an alert in the Work Area of the HREC to which the application has been allocated, informing the HREC Coordinator that an application has been booked in through the CCS (CAS).
- 1.38 Applications that have been allocated to an upcoming meeting of your HREC via the CCS (CAS) will appear under the Work Area alert: **Applications booked in through CAS.**



The screenshot shows a web interface with a navigation bar at the top containing tabs for 'HREC Applications', 'SSA', 'Meetings', 'Amendments', 'Progress Reports', 'Complaints', and 'Other'. Below the navigation bar is a section titled 'Applications booked in through CAS'. This section contains a table with the following columns: 'HREC Reference', 'Short Title', 'Allocated Meeting', and 'Meeting start date'. A 'View' button is located to the left of the first row of data.

HREC Reference	Short Title	Allocated Meeting	Meeting start date
HREC/10/TESTQLD/44	Ainsley Test	16th June hrec - 05/07/2010	05 July 2010

- 1.39 Under this heading is a list of all HREC applications that have been booked in through the CCS (CAS) and allocated to one of your meetings where a CCS (CAS) slot is available. This alert is cleared when the study has been recorded as either 'valid' or 'invalid' on the **Application-Validate/Start** page. To view the application, click on the 'View' button. This will take you to the Application – References page. You can then complete the relevant details, upload the online form, check in any documents which haven't been uploaded by the researcher through the online forms, and validate the study.
- 1.40 Once the application has been validated, it can be assigned to a meeting from the **Application-Meetings** page.
- 1.41 An email will be sent from the CCS to all QH RGOs at participating sites once the study has been validated.

Uploaded supporting documents

All Studies

- 1.42 If the applicant has attached electronic copies of their supporting documentation to their online application form (www.ethicsform.org/au), these documents will automatically be uploaded to the Application when you import the online form.
- 1.43 To view the uploaded document, click on the magnifying glass icon next to the document in the '**Uploaded Documents**' column.
- 1.44 If the applicant uploads a newer version of an electronic supporting document to their online form application at www.ethicsform.org/au, 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 clicking the **refresh version** icon next to the current version of that document in the list of 'Documents checked in'. AU RED will keep a copy of all document versions uploaded.
- 1.45 If the researcher uploads an entirely new document into the Online Forms Document tab after the HREC Administrator has uploaded the HREC application , the HREC administrator will need to upload the online form data again (using the same submission code unless the form itself has been modified) in order to pull in the new document.

Validation of Applications

All Studies

- 1.46 An application is accepted as valid if it meets all the following criteria:
- (a) The applicant's checklist has been completed and submitted.
 - (b) All documents relevant to the particular application listed in the checklist have been submitted.
 - (c) All relevant sections and questions in the NEAF application are in English and the print is clearly legible.
 - (d) The NEAF application has been signed by all investigators, the Head of the Department in which the research will be conducted, the educational supervisor /Student Liaison Officer (in the case of research to be conducted by students) and the QH Project Liaison Officer (in the case of research to be conducted by persons external to the QH facility).
 - (e) Signatures may be original, scanned, faxed or electronically inserted into the documents except where original signatures are compulsory eg CTN documents.

SL1: Acknowledgement of receipt of a valid application

AU-RED ALERT

- 1.47 An application is invalid if:
- (i) Major discrepancies are present e.g. the submission is not on the NEAF application, the NEAF is incomplete and/or an information sheet has not been provided
 - (ii) The required supporting documentation (such as protocol, budget details, information sheet & consent form, questionnaires and other tools) is not submitted with the NEAF
 - (iii) The documentation is not signed.

SL2: Acknowledgement of receipt of an invalid application

AU-RED ALERT

- 1.48 Upon receipt of the application, the HREC Administrator should check that the application meets the stated criteria (valid or not valid).
- 1.49 The decision whether or not an application is valid can be made by the HREC Administrator, although if in doubt the Chairperson should be consulted.
- 1.50 For invalid applications the Principal Investigator will be notified in writing by the HREC coordinator that:
- the application will not be accepted for the next meeting and that the application will require further documentation prior to HREC review **or**
 - the PI must supply further information in relation to an application by a specific date for the application to be reviewed at the next meeting **or**
 - the application must be resubmitted through the CCS for reallocation to a certified reviewing HREC.
- 1.51 For applications requiring full HREC review the relevant date (“the validation date”) is the closing date for submissions.
- 1.52 For applications not requiring full ethical review the relevant date (“the validation date”) is the working day on which the complete application, including all relevant signatures and all supporting documents, is delivered to the address of the reviewing body, whether or not the administrator or another member of the reviewing body office staff is present to receive it.
- 1.53 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 will be sent by the HREC Administrator within one week of receipt, via the following letters (SL1 & SL2). The acknowledgement letter /email includes the specific identifying number allocated to the protocol.
- 1.54 A copy of the acknowledgement letter should be sent to the research assistant or study coordinator if such a person has been nominated in the application.

Allocation of applications for ethical review

All Studies

- 1.55 Where able, applications will be forwarded by the Administrator to the expert reviewer/s at least two weeks prior to the meeting of the scientific sub-committee, or at least two weeks prior to the meeting at which the decision is required.
- 1.56 The period of 60 days, within which an ethical decision must be given, begins on:
- the closing date for submissions, for applications requiring full HREC review

- when a valid application is received by the reviewing body, for applications not requiring full HREC review

Single Site Studies

- 1.57 The Administrator will consult with the HREC Chairperson with regards to the need for review of the protocol prior to full review by the HREC, e.g. scientific sub-committee review, primary reviewer or expert review.
- 1.58 When an application has been assigned to a meeting a letter / email should be sent to the investigator notifying them of the meeting date and the need to attend the meeting if required.

Multi-centre Studies

- 1.59 The CCS will have allocated, through AU RED, the study to a reviewing HREC meeting date.
- 1.60 The Administrator will need to validate and assign the study to the allocated meeting.
- 1.61 When an application has been assigned to a meeting a letter / email should be sent to the investigator, by the reviewing HREC, notifying them of the need to attend the meeting if required.

SL4: Acknowledgement application and invitation to a meeting

AU-RED ALERT

Revision of applications following submission

- 1.62 Once a valid application has been made, no revisions may be made prior to the review by the scientific sub-committee, expert reviewers and HREC.
- 1.63 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.
- 1.64 If the applicant considers it necessary to make minor revisions (e.g. correction of typographical errors etc) to the supporting documentation following review by the HREC but before a final ethical decision has been given, these may be included in the applicant's response to the request made by the HREC for further information or

clarification. The changes should be clearly highlighted in the updated documents using Microsoft Word's "Track Changes" function or similar, and the relevant documents given new version numbers and dates and accompanied by a cover letter explaining clearly what the changes are and why these have been made. 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

- 1.65 If the Chairperson 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 application may be rejected, or the revisions may be submitted to the Committee at the next meeting.
- 1.66 For revisions made after a final ethical decision has been given, refer to the procedures for review of amendments in Section 4.

Withdrawal of applications

- 1.67 If an applicant withdraws an application at any time, the application should be treated as no longer valid and the 60 day time frame will no longer apply. The status should be marked "withdrawn" on the database and providing the file is in order, it can be archived. If the applicant wishes to re-submit the application, it should be treated as a new submission.

SL3: Acknowledgement of withdrawal of Application

AU-RED ALERT

Studies not requiring ethical review

- 1.68 Where the Chairperson or Administrator is approached for advice on whether a project falls within the definition of research, and therefore whether an application should be submitted to the HREC, it is recommended that the applicant:
- (i) consult the NHMRC "*National Statement on Ethical Conduct in Human Research*" (2007) and
 - (iii) provide a brief outline of the project in writing to the HREC Office justifying why they are seeking exemption.

- 1.69 Institutions will develop their own site specific Standard Operating Procedures (SOPs) for processing applications not requiring HREC review. This includes low and negligible risk research studies and quality assurance projects. These SOPs will be in accordance with the National Statement on Ethical Conduct in Human Research” (2007) and QH Clinical Audit & Review Standard

http://www.health.qld.gov.au/cpic/documents/clinaudrevstand_v1.pdf

SL5: Proposal not requiring review by HREC

AU-RED ALERT

Exceptional Circumstances Review

All studies

- 1.70 There may be wholly exceptional circumstances where as a matter of public policy, and in the national interest, it is essential that an application should be 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 in a field that is currently the subject of major public anxiety, or 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.
- 1.71 Note that 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. The onus is on the researchers to ensure the timely submission of their application to a HREC and completion of site-specific requirements.

Procedure

Single Site Studies

- 1.72 Applications submitted for review under exceptional circumstances should contain:
- Completed NEAF or original submission if not on NEAF and time factor does not allow time for NEAF to be completed;

- Study protocol and supporting documentation;
 - A request for exceptional circumstances review in writing and containing the reason for requesting review under exceptional circumstances and justification for the request by aligning the protocol with the above categories
- 1.73 The application will be checked by the HREC Administrator for compliance with application procedures and recorded on AU – RED.
- 1.74 The application will be reviewed by the HREC Chair and one or more HREC members. The Chair and additional HREC member/s will be blinded to the other's decision in the initial review. One of these two 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.
- 1.75 If the decision of the Chair and additional HREC member is unanimous that the application qualifies for exceptional circumstances review, the HREC Chair will advise the District CEO or Delegate, through the local RGO, of the recommendation to conduct the research and monitoring responsibilities.
- 1.76 In such circumstances, the Principal Investigator may be exempt from completing an SSA form, subject to local administrative research governance requirements. All approval documents should be signed off by the District CEO or Delegate in accordance with normal approval procedures. At this stage the research may commence.
- 1.77 If there is disagreement between the Chair and the additional HREC member, the protocol will not receive exceptional circumstances review and will be reviewed at a full meeting of the HREC.
- 1.78 The HREC reserves the right to ratify the previous decision, request amendments or clarification, or reject the protocol.

Multi-centre Studies

- 1.79 Applications submitted for review under exceptional circumstances should be submitted to the local RGO as per the normal single ethical review process for multi-centre research and should include:
- Completed NEAF or original submission if not on NEAF and time factor does not allow time for NEAF to be completed;
 - Evidence of a certified HREC approval;
 - Study protocol and supporting documentation

- 1.80 The RGO will review the application and make a recommendation to the District CEO or Delegate
- 1.81 The District CEO or Delegate may grant approval, under exceptional circumstances for a study where:
- A certified HREC has approved the application and it appears to conform to the requirements of the institution / district and
 - Clinical need necessitates urgent approval of the application.

SECTION 2: MEETINGS OF A HUMAN RESEARCH ETHICS COMMITTEE

General policy

- 2.1 All valid applications for an ethical decision should be reviewed at a scheduled meeting of a HREC held in accordance with the following procedures, except where the low or negligible risk circumstances apply.
- 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 A HREC should hold at least 10 scheduled meetings in each year for the purposes of ethical review of applications. Additional meetings may be held where necessary to ensure that an ethical decision on an application is given within the time limit of 60 days from the date of receipt or to discuss matters relating to the establishment or operating procedures of the HREC or for training purposes.
- 2.4 Meetings to review applications are normally held at intervals of one month. A longer interval is permissible when meetings span holiday periods but should not at any time exceed two months.
- 2.5 The schedule of Committee meetings for the year commencing on 1 January should be agreed between the Administrator and the Chairperson by 31 October in the previous year. The schedule should set out the dates, times and venues of meetings, the closing date for applications to each meeting and the number of application copies required for submission. All members and co-opted members of the HREC should be issued with details of the schedule. This requirement applies also to meetings of any Scientific sub-Committees, although it is recognised that it will not be possible to predict the timing of expert external reviews.
- 2.6 The closing dates for applications should normally be no earlier than 25 calendar days and no later than 14 calendar days prior to each HREC meeting or scientific review, whichever occurs first.

2.7 Following approval by the HREC Chairperson, the HREC Administrators should arrange for the HREC membership, HREC Terms of Reference and meeting schedules to be widely publicised to prospective researchers, committee members, venue organisers and universities. Copies of these documents are to be provided to the REGU for the purpose of updating the unit's webpage.

Agenda

2.8 The HREC Administrator prepares the agenda for the meeting generated from AU-RED, which should include at least the following:

- The date, time and venue of the meeting
- Declarations of conflicts of interest relating to items on the agenda
- Confirmation of Minutes of the previous Committee meeting
- Business arising at the previous meeting(s) that the Committee specifically indicated that it wished to consider again
- New Applications for ethical review of new applications to be considered at the meeting
- Applications for ethical review of amended documents/modifications to be considered at the meeting
- Annual, Final Reports and items for noting to be reviewed by the committee
- Reports of Onsite and External Serious Adverse Events to be reviewed by the committee
- Notice of upcoming educational activities that may be of interest to committee members
- Any General Business
- Notification of the date, time and venue of the next scheduled meeting

SF2: Research Ethics Agenda

AU-RED ALERT

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

2.10 The agenda may also include discussion of the following where appropriate:

- General Research ethics issues, for example arising from new guidelines or recent publications
 - Matters relating to the establishment or membership of the HREC
 - Matters relating to Committee procedures.
- 2.11 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 undermine the rigour of the ethical review.
- 2.12 Minutes of the meeting of the scientific sub-committee and/or reports from external expert reviewers should be made available to HREC members prior to the meeting.
- 2.13 Where the HREC has previously delegated authority to the Chairperson or low risk review delegates/committee to give an ethical decision following receipt of further information or clarification from the applicant, the Committee should be notified, via the agenda, of the final decision taken on its behalf.
- 2.14 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
 - If any significant questions of ethical judgement arose, 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 Administrator, in consultation as appropriate with the Chairperson.
- 2.17 A lead reviewer should be provided with a copy of the protocol for the research study to which he/she has been allocated, in addition to the application form and other supporting documentation.
- 2.18 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

- 2.19 The HREC Administrator should normally arrange the distribution of the agenda, applications and other relevant papers for review at the meeting between 7 and 14 days prior to the meeting. In exceptional circumstances, with the agreement of the Chairperson, certain late papers may be tabled at the meeting. Under no circumstances should late initial applications (i.e. those submitted after the HREC closing date) be tabled at the meeting.
- 2.20 All members should receive the NEAF form for each new application, together with all supporting documentation except as follows:
- The protocol for the study should be sent to the lead reviewer(s) and to members with relevant expertise. Other members should review the protocol according to local committee requirements.
 - The Investigator Brochure for an investigational medicinal 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 required.
 - It is helpful to attach a cover sheet to each new application, on which the committee member may record his/her comments.

SF3: HREC Cover Sheet for new Protocols

Attendance of the Principal Investigator or Coordinating Principal Investigator

- 2.21 At the request of a committee member, the Principal Investigator (or CPI for multi-centre studies) may be invited to attend the meeting at which his/her application is to be reviewed, or at subsequent meetings. The purpose of this meeting is for the Principal Investigator (or CPI for multi-centre studies) to respond directly to requests from the Committee for further information, clarification or reassurance. In this way, many issues of concern to the Committee may be resolved at the meeting. Even where further consideration needs to be given by the Principal Investigator (or CPI for multi-centre studies) after the meeting to matters raised by the Committee, his/her attendance to hear the points raised in person may well prove to have been helpful in formulating a satisfactory response.
- 2.22 Where the Principal Investigator (or CPI for multi-centre studies) is unable to attend, it is acceptable for another key investigator or collaborator to attend instead. It is not ethically acceptable for a representative of the sponsor to attend in place of the

Principal Investigator. Other members of the research team or representatives of the sponsor may also express an interest in attending alongside the Principal Investigator (or CPI for multi-centre studies), and this should normally be permitted if the size of the meeting room makes it practicable.

- 2.23 Where speakerphone/teleconference facilities are available in the room to be used for the meeting, the HREC may offer the Principal Investigator (or CPI for multi-centre studies) the alternative of being available by phone at the time of the review. It should be possible for all members present in the room to question the Principal Investigator and hear the responses.
- 2.24 In the case of applications submitted by students, the HREC should consider inviting the educational supervisor/Student Liaison Officer to attend. In addition, where the student is conducting the research under supervision within the hospital, the clinical supervisor may be invited to attend.
- 2.25 It is not the purpose of the Principal Investigator's (or CPI for multi-centre studies) attendance to make a formal presentation of the study, and this should not be permitted.

SL4: Acknowledgement of Application and invitation to meeting

AU-RED ALERT

Minimum membership requirements and meeting attendance

- 2.26 The minimum membership for meetings of an HREC is eight members, as specified in paragraph 5.1.29/30 of the National Statement. The National Statement also states that where there is less than a full attendance of the minimum membership at a meeting, the meeting may proceed provided the Chairperson 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.
- 2.27 A "co-opted" member who is attending in place of a "designated" member should be counted for the purpose of the meeting membership.
- 2.28 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.
- 2.29 If paragraph 5.2.30 of the National Statement has not been satisfied, a Committee meeting, or part of the meeting, may proceed with any other business on the agenda

- as if it were a sub-committee meeting, provided that the Chairperson (or vice-Chairperson or alternate vice-Chairperson) and at least one other member is present.
- 2.30 The Administrator should keep a record of attendance, indicating which members and co-opted members were present for the discussion of each application for ethical review.
- 2.31 Where the Administrator of an HREC 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 Chairperson and consider the following options:
- Co-opting additional members who have the necessary expertise to fulfil the membership criteria
 - Postponing and re-arranging the meeting
 - Cancelling the meeting.
- 2.32 If the meeting is postponed or cancelled, the Administrator should consider with the Chairperson the need to ensure that the applications listed on the agenda are processed within the recommended time limit.

Co-opted members

- 2.33 A HREC may co-opt additional members in each category at any meeting of the HREC for the purposes of that meeting. A person may be co-opted as a member only if he/she has had prior experience and/or training as a member of an HREC and/or has expert scientific or clinical knowledge relevant to the protocols being discussed.
- 2.34 Local procedures for co-opting members within each health service district are the responsibility of the HREC Administrator. The HREC Administrator should maintain records of members within the area who would in principle be willing to be co-opted where required.
- 2.35 To ensure a “co-opted” member is provided with indemnity and insurance coverage and is aware of their roles and responsibilities they should be formally appointed to the HREC.

Written comments from members

- 2.36 A member who is unavailable to attend a meeting may submit comments in writing on any agenda item. These should normally be received by the Administrator at least three working days prior to the meeting so that copies may be made available in advance to members. Where later comments are received, they may be tabled at the meeting at the discretion of the Chairperson. The Minutes should record the submission of written comments.
- 2.37 A member who submits written comments but does not attend the meeting counts towards the quorum.

External Expert reviewers

- 2.38 A HREC may seek the written advice of an expert reviewer on any aspects of an application that are relevant to the formation of an 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 required 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. For industry sponsored, funded studies the cost of the external expert review should be borne by the sponsor.
- 2.39 Advice from expert reviewers may be sought at any time by the HREC.
- 2.40 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.
- 2.41 The Administrator or Chairperson should ensure that the expert reviewer(s) has/have declared any conflict of interest and agreed to QH terms of Confidentiality
- 2.42 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.
- 2.43 The expert reviewer may be invited to attend the meeting in person for discussion of the application concerned. The attendance of the expert reviewer and the substance of his/her advice at the meeting should be recorded in the Minutes. The expert reviewer should not have a vote in the decision taken by the Committee.

SF4: Agreement for the Conduct of Expert Review

SF9: HREC Request for QH Expert Review of Research Proposal

SF5: QH External Expert Research Proposal Review Report Form

SF6: VMIA “Expert Review Proforma: Pharmacology & Toxicology”

http://www.vmia.vic.gov.au/skillsEDIT/clientuploads/48/pharm_tox_ER%20proforma_1.xls

SF7: VIMA “Expert Review Proforma: Formulation / Manufacturing”

http://www.vmia.vic.gov.au/skillsEDIT/clientuploads/48/formulation_manufacturing_ER%20proforma_1.xls

SF8: VIMA “Expert Review Proforma: Immunology”

http://www.vmia.vic.gov.au/skillsEDIT/clientuploads/48/immunology_ER%20proforma_1.xls

Research involving adults with impaired capacity to consent

2.44 The Principal Investigator (or CPI for multi-centre studies) is required to obtain approval from the Queensland Civil and Administrative Tribunal (QCAT) in circumstances where the participant of the trial may be, by reason of physical or mental incapacity, incapable of giving informed consent to participation. This approval process occurs post HREC approval.

What is impaired decision-making capacity?

2.45 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.

2.46 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.

- 2.47 Sections 65, 68, 72 and 74 of the Guardianship and Administration Act 2000 cover participation in “special medical research or experimental health care”.
- 2.48 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 give consent, written application to the Queensland Civil and Administrative Tribunal must be undertaken. The Queensland Civil and Administrative Tribunal contact details are:
- Queensland Civil and Administrative Tribunal
GPO Box 1639
Brisbane Qld 4001
Telephone: 1300 753 228
Facsimile: 07 3221 9156
Email: applications@qcat.qld.gov.au
- <http://www.qcat.qld.gov.au/index.htm>
http://www.qcat.qld.gov.au/Formsfinal/F16_Ap_con_c.rsrch.pdf

Access to Confidential Health Information held by QH:

- 2.49 When researchers require access and use of identifiable or re-identifiable data and confidential information, without consent, for the purposes of research, the provision of the Public Health Act 2005 (Qld), s282 must be considered.
- 2.50 This includes health information held and owned by QH from the:
- Cancer Registry
 - Perinatal Statistics Collection
 - Pap Smear Register
 - Register Screening Histories of Women
 - Inpatient Data/records (including AusLab)
 - Pathology samples from QH Clinical and State-wide Services (CaSS)
 - Any other Data base systems / hard copy charts held by QH.
- 2.51 Prior to commencing the research, the researcher must:
- Seek HREC approval for the protocol;
 - Complete an SSA Form;
 - Discuss data requirements with the data custodian;
 - Complete a PHA application for release of data; and

- Submit PHA application to the REGU

Further information can be accessed at:

http://www.health.qld.gov.au/ohmr/html/regu/aces_conf_hth_info.asp

Declarations of interest

- 2.52 Members and co-opted 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 that meeting. Such a declaration may be made orally at the meeting, prior to the matter being considered, or in writing to the Chairperson prior to the meeting.
- 2.53 Where the member concerned is the Principal Investigator 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 resumes.
- 2.54 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.
- 2.55 The Minutes should record any declaration of interest and the decision of the Committee on the procedure to be followed.
- 2.56 Any conflict of interest pertaining to researchers, institutions, HREC members & all other stakeholders should be considered in accordance with QH Standard 5: Conflict of Interest in Research 2010 and the QH Research Management Policy 2010.

Confidentiality of proceedings

- 2.57 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.

2.58 The Terms and Conditions of Appointment for members and co-opted members include requirements to keep confidential the business of the HREC.

Conduct of business and decision-making

2.59 The Chairperson is responsible for the conduct of the business and for ensuring that the Committee reaches clearly agreed decisions on all matters. Where the Chairperson is unavailable, the meeting should normally be Chaired by the vice-Chairperson or, if the vice-Chairperson is also unavailable, by the alternate vice-Chairperson.

2.60 All members present, both expert and lay, should be allowed reasonable opportunity to express relevant views on matters on the agenda.

2.61 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 taken.

2.62 Where any member wishes to record his/her formal dissent from the decision of the Committee, this should be recorded in the Minutes.

Responsibilities of the Administrator

2.63 The secretary to the meeting will normally be the Committee Administrator or an assistant administrator.

2.64 The responsibilities of the Administrator or assistant administrator in relation to HREC meetings are as follows:

- (i) Publishing the schedule of HREC meetings
- (ii) Preparing the agenda
- (iii) Allocating lead reviewers (where this is the practice of the HREC)
- (iv) Distributing the agenda and papers
- (v) Inviting Principal Investigators and, where appropriate, supervisors to attend and making the necessary arrangements
- (vi) Preparing the venue
- (vii) Recording apologies for absence prior to the meeting
- (viii) Raising with the Chairperson any concern that a meeting may not be quorate
- (ix) Recording attendance by members, co-opted members and referees for the discussion of each application for ethical review

- (x) Advising the meeting as necessary on compliance with standard operating procedures
- (xi) Making a written record of the meeting
- (xii) Preparing the Minutes of the meeting for review and approval at the following meeting
- (xiii) Notifying applicants of decisions taken at the meeting and taking other follow-up action as necessary.

Minutes

2.65 The Minutes of the HREC meeting should be prepared by the secretary to the meeting, in consultation with the Chairperson and other members as necessary, and approved by the Chairperson within five days following the meeting.

2.66 The Minutes of the HREC meeting should be saved in AU RED.

SF9: HREC Minutes

AU-RED ALERT

2.67 In relation to applications for ethical review or notices of substantial amendment, the Minutes should contain a record of the following, whether in the main text of the Minutes or in attachments:

- (i) The members, co-opted members and external expert reviewers present for the review
- (ii) Any interests declared, and the decision of the Committee on the participation of the member or co-opted member concerned
- (iii) The submission of written comments by members or co-opted members
- (iv) The substance of any advice given by an expert reviewer
- (v) The decision of the HREC on the application
- (vii) A summary of the main ethical issues considered linked to the National Statement.
- (viii) In the case of further information being requested, any special approval conditions or additional advice to be given to the applicant
- (ix) In the case of an unapproved decision, the reasons for the decision by reference to the National Statement

- (x) In the case of a provisional decision, the further information requested by the HREC and the arrangements for considering the information and confirming the final decision of the HREC
 - (xi) Where no decision is reached, the issues on which further advice is required from a external expert reviewer
 - (xii) Where an unapproved decision is given on a notice of amendment, the reasons for the decision, and any delegation of responsibility for giving the decision of the HREC on a modified amendment
 - (xiii) The outcome of any vote taken.
 - (xiv) Any formal dissent from the decision of the HREC by a named member, with reasons.
- 2.68 The Minutes should be submitted to the following 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 Chairperson.
- 2.69 The Minutes are confidential to the HREC and should not be disclosed to applicants, sponsors or host organisations. For the purposes of HREC governance, copies of Minutes should be made available to the appointing authority for the HREC.
- 2.70 The executive of the authority (District CEO/delegate) should be provided with an Annual Report which contains details of all applications approved by the HREC and any other requested information required for District/facility reporting.

SECTION 3: GIVING AN ETHICAL DECISION

Policy requirements

- 3.1 An HREC is required to give an ethical decision on a submitted application within 60 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 The policy of QH is that these requirements will apply to all research reviewed by QH HRECs.

Decisions available to the HREC

- 3.3 An HREC should reach one of the following decisions on any application reviewed at a meeting:
- (i) Final decision. The Committee may reach a final decision on the application at the meeting. This decision may be either:
 - (a) Approved or
 - (b) Not approved
 - (ii) Further information/modification requested. The Committee may decide that a provisional approval can be given subject to receipt of a satisfactory response to a request for further information/clarification and/or modification.

The final decision is then:

- (a) Further information/modification requested approved or
 - (b) Further information/modification requested not approved or
 - (c) Further information/modification response not complete
- (iii) No opinion pending consultation with referee. The Committee may decide that no decision can be given until an expert reviewer has been consulted.
 - (iv) 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.

- (v) Not requiring review by HREC. The Chairperson may decide that the application does not require review by the HREC (e.g. Low and negligible risk research, quality assurance projects)
- 3.4 The Chairperson should ensure that one of the above decisions is made on every application considered at an HREC meeting.
- 3.5 Where the HREC decides that further information or clarification is required, the Chairperson 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 NEAF but should be asked to provide a cover letter clearly addressing the questions asked by the HREC and must provide all the revised documentation eg study protocol, participant information sheets and consent forms etc in both 'track' changes and 'clean' forms.
 - Delegation of responsibility for considering the further information and confirming the HREC's 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 Chairperson only.
 - The questions asked by the HREC are based on references to the National Statement.
- 3.6 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.
- 3.7 The secretary to the meeting 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.
- 3.8 In making an ethical decision, the Chairperson or delegate may decide to allow other persons access to HREC application 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.

Notification of the decision to the Principal Investigator (or Coordinating Principal Investigator)

3.9 The Administrator should ensure that, following confirmation of the Minutes by the Chairperson, notification of the decision is sent to the Principal Investigator (or Coordinating Principal Investigator for multi-centre studies) in writing within 5 working days of the meeting. One of the following letters should be used:

AU – RED ALERT

SL6: Approval of New Application

SL7: Request for Further Information or clarification in order to reach a final decision

- 3.10 Initial HREC approval notification to the researcher may be via email from the HREC administrator or HREC Chairperson.
- 3.11 The following information should in all cases be included in the letter or in enclosures for the ethical and scientific approval of a new application:
- The decision reached by the Committee
 - A list of all documents reviewed at the meeting, giving version numbers and dates.
 - A deidentified list of the membership of the committee which includes the membership category, gender and institutional affiliation.
 - Any interests declared by members who were present for the discussion of the application.
- 3.12 The letter should also include the HREC's decision on any relevant issue on which the applicant has specifically asked for its decision.
- 3.13 It is not necessary to include all the questions raised at the meeting, such as requests by lay members for explanation of technical points. However, it is important to record for future reference any ethical concerns, with reference to the National Statement, that the HREC collectively discussed and resolved at the meeting.
- 3.14 The letter should not attribute particular comments or questions to individual members of the Committee.

Letters giving the HREC's final decision

3.15 The final decision of the HREC will form part of the recommendation to the District Executive for authorisation to conduct the Research at the QH site. The HREC approval letter should be posted to the applicant no later than 60 calendar days from the validation date. The letter contains standard conditions for research approved by an HREC.

AU – RED ALERT

SL6: Approval of application

3.16 Additional information sent to researchers following HREC approval include:

AU-RED ALERT

SF10: Composition of HREC

SF11: Researcher Commencement Form

- 3.17 The District CEO or Delegate is the person to grant authorisation of research projects on humans to be conducted within or in association with QH Districts. The research must not commence until this authorisation has been granted.
- 3.18 Any additional approval conditions specified by the HREC for a particular application, for example a requirement for more frequent progress reports, should be included in the letter.
- 3.19 Where the final decision is unapproved, 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.

Provisional decision and request for further information

Delegation of responsibility by the HREC

- 3.20 Where the HREC requests further information from the applicant, it should decide at the meeting the procedures for considering that information and for confirming the HREC's final decision. These responsibilities should normally be delegated to one of the following:
- Where the lead reviewing HREC has made the decision to request the clarification of information, the provision of further information to the HREC and/or modification/s to the study, the lead reviewing HREC will establish a procedure for

considering interim correspondence received from the Coordinating Principal Investigator which may include one of the following:

- Delegation of the authority to review the interim correspondence and approve the study between meetings at the discretion of the Chair alone;
- Delegation of the 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;
- Delegation of the authority to review the interim correspondence and approve the study between meetings at the discretion of a sub-committee of the HREC;
- Consideration of the interim correspondence at a further meeting of the HREC (in exceptional circumstances or where those delegated authorisation to review interim correspondence recommend reference back to a further meeting of the HREC);
- Delegation of the authority to the HREC administrator.

3.21 To provide suitable oversight of this delegated authority to review the interim correspondence and approve the study between meetings, the HREC must ratify at the next available meeting of the final decision taken on its behalf, including the applicant's response and the reason for the decision taken.

3.22 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 Chairperson 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.

3.23 Exceptionally, the HREC may decide that the information should be considered at a further meeting of the HREC. When taking this course, the HREC should take into account careful consideration of the 60-day time limit. If the information is received following the closing date for submitting papers to a scheduled meeting of the HREC, it could therefore be necessary to arrange an additional meeting.

Suspension of 60 day time period

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- 3.24 The 60-day time period should be suspended from the date on which the request for further information was sent to the applicant. It should be re-started when a complete response is received.
- 3.25 Where the response arrives piecemeal, the relevant date is the date on which the final part of the response is received.
- 3.26 The relevant date is therefore the date on which a complete response is received in the HREC office, not the date on which the information is considered by the HREC and judged to be acceptable or otherwise.
- 3.27 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.

Requirement for a complete response

- 3.28 If the applicant's response is incomplete or does not appear to fully address the matters raised, if considered necessary, the HREC is entitled to insist on a complete response before confirming its final decision. The Administrator should write to the applicant, setting out the further information or clarification still required. The 60-day time period should remain suspended until a complete response is received.
- 3.29 The applicant should be allowed a period of three months or two meetings to respond to the request for further information. The applicant should be reminded that if no response is received within four months, the HREC will consider the application to be withdrawn and will require the applicant to submit a new application.

Final decision following consideration of the information

- 3.30 On receipt of a complete 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 above should be followed.

Further advice from a External Expert Reviewer(s)

- 3.31 Where a 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:
- Advice 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 may notify the applicant of the issues of concern to the HREC, but should not at this point request further information or clarification.
- 3.32 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 Chairperson or the Administrator should be appointed to identify a suitable expert reviewer urgently following the meeting.
- 3.33 The Chairperson or Administrator should initially contact the prospective expert reviewer(s) by phone or e-mail 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. Advice should be given about confidentiality.
- 3.34 For industry sponsored, funded studies the cost of the external expert review should be borne by the sponsor.
- 3.35 Once a suitable expert reviewer has been identified, the Administrator should write to the expert reviewer. This letter should be as specific as possible about the issues of concern to the HREC and the expert advice required using any of the following forms for all clinical phase trials in these categories.

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SL8: Advice to Researcher/s regarding delay in HREC decision pending consultation with Scientific Subcommittee/Expert Referees

SL9: HREC Request for QH External Expert Review of a Research Proposal

SF4: Agreement for the conduct of Expert Review

SF5: QH External Expert Research Proposal Review Report Form

SF6: VMIA “Expert Review Proforma: Pharmacology & Toxicology”

http://www.vmia.vic.gov.au/skillsEDIT/clientuploads/48/pharm_tox_ER%20proforma_1.xls

SF7: VIMA “Expert Review Proforma: Formulation/Manufacturing”

http://www.vmia.vic.gov.au/skillsEDIT/clientuploads/48/formulation_manufacturing_ER%20proforma_1.xls

SF8: VIMA “Expert Review Proforma: Immunology”

http://www.vmia.vic.gov.au/skillsEDIT/clientuploads/48/immunology_ER%20proforma_1.xls

- 3.36 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 5 working days of the meeting. The expert reviewer should be asked to respond in writing within a further 14 days.
- 3.37 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 decide to give a decision on the application at this point, or request further information from the applicant. Where an approved or unapproved decision is given, the procedures set out in paragraphs 3.13 - 3.18 apply and one of the following letters should be used.

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SL6: Approval of Application

SL10: Unapproved Decision on Protocol given by HREC following Advice from Scientific Sub Committee/ Expert reviewers

SL7: Request for further information or clarification in order to reach a final decision

SL11: Request for further information response not approved

- 3.38 The HREC should not disclose the nature of the reviewer’s advice to the applicant. The decision it reaches on the application is its own. It may not disclose the identity of the reviewer/s except with his/her express permission.

Matters relating to the confirmation of an approved decision

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

- 3.39 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 CTN and CTX schemes), the Special Access Scheme and approval of Authorised Prescriber.
- 3.40 Unapproved therapeutic goods have undergone little or no evaluation of quality, safety or efficacy by the Therapeutic Goods Administration (TGA). As such, use of some of these products is/are considered to be experimental and potentially carries some risks that have not been defined in the Australian context. HREC should be guided by the principles outlined in the National Statement in assessing the risks and precautions in research involving humans.
- 3.41 The roles and responsibilities required of HRECs under the Therapeutic Goods legislation can be found at: <http://www.tga.gov.au/docs/html/hrec.htm>
- 3.42 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”
- 3.43 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 Principal Investigator. 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;
 - CTX: The TGA reviews summary data about the therapeutic good (medicine or medical device). The TGA then provides comment to the HREC about the product and stipulates the minimum data which must be provided to the HREC. The HREC and Institution may require additional information to be provided in support of an application;
 - HRECs are responsible for reviewing clinical trial protocols for both CTX and CTN. Responsibility for the conduct of the trial rests with the Principal Investigator and approval of the trial rests with the Institution or body where the trial is to be conducted.

- In approving a trial protocol, under both CTN and CTX, the HREC is assuming responsibility for 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.

Insurance and indemnity

3.44 Refer to QH Research Management Policy

Updated safety information

3.45 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 Principal Investigator (or CPI for multi-centre studies) if they become aware of such circumstances.

Further review following a 'not approved' decision

- 3.46 Where an HREC has given a 'not approved' decision on an application, the applicant may seek further review as follows:
- A new application may be submitted to the same HREC (and no other HREC), taking due account of the HREC's concerns. This should be processed and reviewed in the same way as any other new application.
 - The applicant may lodge a complaint with the HREC Chair and a process should be followed as outlined in Section 10.

Confidentiality

- 3.47 Once an application has been validated for review, all further correspondence with the applicant relating to the application should be treated confidentially by the HREC.
- 3.48 No copies of letters should be sent directly by the HREC, giving the decision reached by the HREC, or requesting further information, to the sponsor(s) of the research
- 3.49 As per National Statement 5.2.27 and 5.3.3, if requested, copies of letters giving the decision reached by the HREC, or requesting further information, may be sent by the HREC to other HRECs who have an interest in the process.

SECTION 4: AMENDMENTS TO RESEARCH GIVEN DISTRICT AUTHORISATION

4.1 Investigators are required to obtain ethical and/or research governance approval before implementing any amendment to a previously approved study. There are five types of amendments:

- Amendments to the research project which may affect the ongoing ethical acceptability of the project;
- Amendments to the research project which may affect both the ethical acceptability and site acceptability of the project;
- Amendments to the research project which may affect the ongoing site acceptability of the Project ;
- Amendments to the research project which do not affect either the ethical acceptability or site acceptability of the project (e.g. typographical errors, addition to study team).
- Amendments for Urgent Safety Measures

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

All studies

4.2 These are amendments that, as a condition of HREC approval, the Site Principal Investigator (or Coordinating Principal Investigator for multi-centre studies) is required to submit a request for approval of the proposed amendment to the authorising HREC. Amendments that require approval by a HREC include changes to the following:

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

4.3 Amendments which may affect the ongoing ethical acceptability of a project are considered major (substantial) amendments and should be reflected in a cover letter from the principal investigator, stating the changes and reasons for the changes. The cover letter and all updated supporting documentation should be uploaded onto the online forms. Two copies of the updated documents should be provided – one with ‘track changes’ and one ‘clean’ copy. A revised NEAF should not be submitted. Hard copies of the cover letter and all relevant updated documents (e.g. protocol,

participant information sheets etc) should also be submitted to the HREC coordinator as required.

- 4.4 The HREC may require further clarification or information regarding the amendment prior to granting approval. The applicant should respond to these queries promptly in writing. The amendment can be implemented once HREC approval is granted.
- 4.5 For all studies, the outcome of the HREC review and any revised documentation pertaining to the research project must also be submitted by the Site Principal Investigator to the relevant site RGO, for the Health Service Districts noting.

Amendments to the Research Project which may affect both the ethical acceptability and site acceptability of the project

All studies

- 4.6 Amendments which may affect both the ongoing ethical acceptability and site acceptability of a project are considered major (substantial) amendments
- 4.7 Amendments containing a cover letter and all updated supporting documentation should be uploaded onto the online forms.

Multi-centre studies

- 4.8 Where a proposed amendment to the research project may affect both the ethical acceptability and site suitability of the project, the CPI must firstly submit an amendment request to the (authorising) HREC as per '*Amendments which may affect the ethical acceptability of the project*'. The HREC will review the amendment request according to standard procedures and will notify the CPI in writing of its decision.
- 4.9 Amendments should be reflected in a cover letter from the Coordinating Principal Investigator, 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 Coordinating Principal Investigator). Updated documents should be uploaded in two forms - one with 'track changes' and one 'clean' copy. Hard copies of the cover letter and all relevant updated documents must be submitted to the HREC coordinator, as required as per normal authorising HREC procedure.
- 4.10 Substantial amendments (as per glossary) should normally be reviewed at meetings of both the scientific sub-committee of the HREC and the HREC. They may not be reviewed by the Chairperson acting alone.
- 4.11 The amendment cannot proceed until site authorisation is granted.
- 4.12 Once HREC approval has been given for the amendments, copies of the HREC approval letter, a cover letter and all relevant updated documents must be uploaded

through the online form website by the Site Principal Investigators prior to submission to each RGO for authorisation to implement the amendment at the site. Updated documents should be uploaded in two forms - one with 'track changes' and one 'clean' copy. Hard copies of the cover letter and all relevant updated documents must be submitted to the RGO, as required as per normal authorising RGO procedure.

Single site studies

- 4.13 Where a proposed amendment to the research project may affect both the ethical acceptability and site suitability of the project, an amendment request must be submitted in writing to the HREC and RGO by the Site Principal Investigator.
- 4.14 The Site Principal Investigator must make an amendment request to the HREC prior to informing the RGO.
- 4.15 The HREC will review the amendment request and notify, in writing, the Site Principal Investigator of the outcome of its review. The site investigator will be required to send a copy of this letter to the RGO, to notify them of the outcome of the HREC review of the amendment.
- 4.16 Upon receipt of the amendment request, the RGO will review the amendment and determine whether District CEO or Delegate authorisation is required to implement the amendment at the HSD site.
- 4.17 The RGO will notify the site investigator as to whether or not authorisation has been granted for the amendment to be implemented at that site. Authorisation to implement the amendment will only be granted when evidence has been provided of HREC approval.
- 4.18 The Site Principal Investigator may not implement the amendment until the RGO has provided written notification that the amendment has been authorised at the HSD site.

Amendments to the Research Project which may affect the ongoing site acceptability of the Project

All studies

- 4.19 These are amendments which only impact upon the suitability of the research to be conducted at a particular site. Amendment requests for an authorised research project may be submitted directly to the Research Governance Office/r (by-passing the HREC), by the Site Principal Investigator, only when the amendment requires:
 - A change to **one or more** of the following sections of the QH SSA (which relate to the specific site **only**):

- Section 4 – Training
 - Section 6 – Anticipated start and finish dates
 - Section 8a(ii), b(ii), c(ii) – Medicines Australia Standard Indemnity Form(s)
 - Section 8a(iii), b(iii), c(iii) – Evidence of adequate insurance cover
 - Section 8d – Medicines Australia Standard Clinical Trial Agreement(s)
 - Section 11 – Departments and services involved in the research
 - Section 13 – QH account number(s) / cost centre details
 - Section 14 – Finance authorisation
 - Section 13 (a-f) – Declarations and authorisations.
- 4.20 Amendments which may affect the ongoing site acceptability of a project should be reflected in a cover letter from the Site Principal Investigator, 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 Site Principal Investigator). Updated documents should be uploaded in two forms - one with 'track changes' and one 'clean' copy. Hard copies of the cover letter and all relevant updated documents must be submitted to the RGO, as required as per normal authorising RGO procedure.
- 4.21 Upon receipt of the written request for a site amendment, the RGO will determine whether authorisation from the District CEO or delegate is required or if RGO approval only is necessary. The RGO will notify the Site Principal Investigator as to whether or not authorisation has been granted for the amendment to be implemented at the site.
- 4.22 The Site Principal Investigator may commence the amendment at the site only once notification of amendment authorisation has been received.

Minor amendments to the Research Project which do not affect either the ethical acceptability or site acceptability of the project (e.g. typographical errors, addition to study team)

All studies

- 4.23 Amendments which do not affect either the ethical acceptability or site acceptability of the project (as per glossary minor amendments) should be uploaded through the online forms and if required, submitted in hard copy to the HREC coordinator. These should include a cover letter from the Site Principal Investigator (or Coordinating Principal Investigator for multi-centre studies), stating the changes and reasons for changes, and all relevant updated documents. Updated documents should be

submitted to the HREC administrator in two forms - one with 'track changes' and one 'clean' copy. An updated NEAF should not be submitted.

- 4.24 If unsure of the applicability of the amendment, Site Principal Investigators (or Coordinating Principal Investigators for multi-centre studies), are encouraged to contact the authorising HREC Administrator to discuss the amendment.
- 4.25 For all studies, the outcome of the HREC review and any revised documentation pertaining to the research project must also be submitted by the Site Principal Investigators to the relevant site RGO, for Health Service Districts noting.

Amendments for Urgent Safety Measures

All studies

- 4.26 Where it is necessary to eliminate an immediate hazard to the research participants, amendments to the research project may be implemented without prior full HREC review and authorisation from the District Manager/delegate (if necessary). As soon as possible, the implemented amendment should be submitted to the HREC and RGO.

General policy

- 4.27 Substantial amendments (as per glossary) should normally be reviewed at meetings of both the scientific sub-committee of the HREC and the HREC. They may not be reviewed by the Chairperson acting alone, unless circumstances such as 4.25 apply.
- 4.28 Amendments that are not substantial do not require full ethical review. It is the responsibility of the Chairperson or Administrator, in consultation with other members where necessary, to determine whether or not an amendment is substantial. The Principal Investigator is to notify the site RGO of the outcome of the HREC review decision about the amendment.

Revision of the application before the commencement of the research

- 4.29 If an investigator proposes to revise their HREC application, protocol or any other supporting documentation, prior to commencing the study, but after the HREC has given approved decision, if this revision is considered a "substantial amendment" then the same procedures apply as for review of substantial amendments submitted after commencement.

Deciding whether an amendment is substantial

- 4.30 It is the responsibility of the Chairperson or Administrator of the relevant authorising HREC to decide whether or not a proposed amendment is substantial (as defined in the glossary) and requires ethical review. The Administrator has the discretion to make this decision on behalf of the HREC in straightforward cases. However, where the Administrator is in any doubt about the designation of an amendment, he/she should invite the Chairperson to review the documents. Other members may be consulted where necessary or in exceptional cases the documents may be considered at a HREC meeting.
- 4.31 In making this judgement, consideration needs to be given to whether the proposed changes will affect the research “to a significant degree”. Particular account should be taken of any implications for the safety or welfare of participants, and of any information that participants might require to give informed consent to continue to participate in the research as amended. It is recommended that where there is any doubt about the potential implications of the amendment for participants, it should be treated as a substantial amendment and ethically reviewed by the HREC.
- 4.32 Where it appears that the amendment may significantly affect the scientific value of the trial, for example because it modifies the recruitment targets, the selection criteria or the data analysis, the HREC may request that the applicant provides evidence of further scientific review in support of the amendment.

Further information or clarification from the Applicant

- 4.33 The applicant may be invited to submit a modified amendment taking account of the HREC’s concerns. The members present at the meeting may delegate responsibility to the Chairperson to give an approved decision of the amendment if it is subsequently modified in a way that meets all the concerns of the HREC.

Amendments requiring submission of a new Application

- 4.34 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 an unapproved decision and instead request submission of a

new application for full ethical review. 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 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)
- extension of a drug trial into an open-label trial, i.e. all patients to receive study drug.

Decision re amendments

4.35 The decision reached will be:

- Final decision. The Committee may reach a final decision on the amendment at the meeting. This decision will be either:
 - (a) Approved or
 - (b) Not approved
- Further information/modification requested. The Committee may decide that a provisional approval can be given subject to receipt of a satisfactory response to a request for further information/clarification and/or modification.
 - The final decision is then:
 - (a) Further information/modification requested approved or
 - (b) Further information/modification requested not approved or
 - (c) Further information/modification response not complete
- 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 amendment application is so incomplete that they are unable to review the amendment and the researcher must submit the amendment again as a new submission.

- Not requiring review by HREC. The Chairperson may decide that the amendment does not require review by the HREC
- 4.36 The HREC Administrator / RGO should notify the Principal Investigator or Coordinating Principal Investigator for multi-centre studies of the decision using one of the following letters:

AU – RED ALERT

SL13: Approved decision of post authorisation amendment

SL14: Unapproved decision of post authorisation amendment with options for further review.

SECTION 5: REVIEW OF RESEARCH INVOLVING ONLY LOW OR NEGLIGIBLE RISK

5.1 The National Health and Medical Research Council (NHMRC) “National Statement on Ethical Conduct in Human Research 2007” recognises that human research involves a wide range of activities that have variable risks and potential benefits. The “National Statement” establishes different levels of ethical review, based on the degree of risk involved. There are three levels of risk:

- Harm;
- Discomfort;
- 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.

Negligible Risk Research

5.3 The National Statement Section 2.1.7 describes research as “negligible risk” where there is no foreseeable risk of harm or discomfort; and any foreseeable risk is not more than inconvenience to the participants. Where the risk, even if unlikely, is more than inconvenience, the research is not negligible risk. The National Statement describes inconvenience as the least form of harm that is possible for human participants in research. The most common examples of inconvenience in human research are filling in a form, participating in a de-identified survey or giving up time to participate in a research activity.

5.4 Institutions may choose to exempt from ethical review research that:

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

Low Risk Research

5.5 The National Statement Section 2.1.6 describes research as “Low Risk” where the only foreseeable risk is one of discomfort. Discomforts may include minor side-effects

of medication, discomforts related to measuring blood pressure or anxiety induced by an interview. Where the risk, even if unlikely, is more serious than discomfort, the research is not low risk.

5.6 Examples of situations that may qualify for low risk review are

- *Studies that involve healthy volunteers (adults and/or minors) and;*
- *An intervention that involves no more than discomfort to participants, such as, minor side effects of non experimental medication, discomforts related to blood pressure measurements, and anxiety induced by an interview*

5.7 It should be noted that any of the above situations have the potential to become sensitive and may therefore be required to be submitted to the HREC for full Committee review, such as

- *the use of discarded body tissue is a sensitive issue within many Aboriginal groups*
- *social, cultural or religious issues.*
- *potential risks to non-participants, for example, risk of distress to participants family member(s) or infectious disease risks to the community*

5.8 Examples of situations which would not qualify for low risk review (National Statement 5.1.6)

- All research that involves more than low risk;
- Research falling under the following chapters of the National Statement ('except where research on collections of non-identifiable data under these chapters satisfies the conditions for exemption from review' – refer National Statement 5.1.22 and 5.1.23)
 - *Chapter 3.3: Interventions and Therapies, including clinical and non-clinical trials, and innovations*
 - *Chapter 3.5: Human Genetics*
 - *Chapter 3.6: Human Stem Cells*
 - *Chapter 4.1: Women who are pregnant and the human fetus;*
 - *Chapter 4.4: People highly dependent on medical care who may be unable to give consent*
 - *Chapter 4.5: People with a cognitive impairment, an intellectual disability or mental illness.*
 - *Chapter 4.7: Aboriginal and Torres Strait Islander Peoples;*
 - *and some categories of research falling under Chapter 4.6: People who may be involved in illegal activities*

Procedure for review of research exemption from full ethical review

Single site studies

- 5.9 Institutions may establish non-HREC levels of ethical review for low risk. The levels of ethical review may include, but need not be limited to:
- a. review or assessment at departmental level by the head of department;
 - b. review or assessment by a departmental committee of peers (with or without external or independent members);
 - c. delegated review with reporting to an HREC; or
 - d. review by a subcommittee of an HREC.
- 5.10 It is the institution's responsibility to determine which level of ethical review process is implemented for low and negligible risk research and to create site specific Standard Operating Procedures relating to Low and Negligible Risk Research review processes. Researchers should consult with their local HREC office / RGO for advice on where to submit their low and negligible risk research application.
- 5.11 For all low and negligible risk research studies, the "Checklist for Research that is Exempt from full HREC review" and "Application for Ethical Review of Negligible or Low Risk Research" must be completed and submitted to the institution's low and negligible risk review panel.
- 5.12 Researchers are encouraged to contact the local HREC office / RGO to gain an independent assessment of whether the project satisfies the criteria for alternate review rather than that of a full HREC before proceeding with their application.
- Researchers complete the "Checklist for Research that is Exempt from full HREC review" http://www.health.qld.gov.au/ohmr/documents/low_risk_app.doc
 - Researchers complete the "Application for Ethical Review of Negligible or Low Risk Research" http://www.health.qld.gov.au/ohmr/documents/low_risk_app.doc
 - Researchers submit the completed 'Checklist for Research that is Exempt from full HREC review' and the 'Application for Ethical Review of Negligible or Low Risk Research' to the institution's Low Risk Review Body or delegate.
 - If the reviewing panel deems that the research does not qualify for exemption from full ethical review they should notify the principal investigator and refer the investigator to the HREC for advice on the process for full HREC review.

SF13: Checklist and application for Exempt and Low Risk Research

http://www.health.qld.gov.au/ohmr/documents/low_risk_app.doc

- 5.13 If the decision of the reviewing panel is unanimous that the application qualifies for negligible or low risk review, the RGO or delegate will advise the investigator that approval has been granted. At this stage the research may commence
- 5.14 If the reviewing panel considers that the application poses more than low risk (even if unlikely), the application will not receive negligible or low risk approval and will be reviewed at a full meeting of the HREC

Multi-centre studies

- 5.15 To ensure standardisation of review and monitoring procedures, if a Coordinating Principal Investigator wishes to submit a multi-centre negligible risk or low risk research study through the single ethical review process, for review and approval by a certified HREC, a LNR research application form must be completed and submitted as per normal procedure for multi-centre studies for single ethical review through a HREC.
- 5.16 Individual SSA forms will need to be completed and submitted to the RGO at each participating site.

Uploading negligible and low risk research to AU RED

- 5.17 It is highly recommended that all "Low & Negligible Risk" applications be uploaded on AU-Red. This allows for noteworthy reports to be developed, with relation to the substantiation of your workload, tracking of the types of research types.

Process

- Create a 'new application'.
- Select 'other' as the "Study type"
- Enter 'Low / negligible risk research' in "Study Type description"
- Enter the rest of the details and click 'register application'
- On the 'Details' tab screen enter the details manually
- Follow through registering the application as normal.
- It is suggested that a 'Chairperson's meeting' be created and the application assigned to the 'Chairperson's meeting' in order for a decision to be generated.

SECTION 6: RESEARCH INVOLVING MATERIAL FROM CORONERS' AUTOPSIES

- 7.1 Research involving access to coronial material must be referred to the Queensland Health Forensic and Scientific Services Human Research Ethics Committee (FSS-HEC) for ethical and legal approvals. This also applies to clinical research projects where there is a component involving coronial material. In this context, examples of coronial material include tissues from coronial autopsies, slides and blocks, blood samples, autopsy reports and other documents and data relating to coronial autopsies.
- 7.2 The use of material from coronial autopsies for research requires the approval of the State Coroner. If the research involves access to coronial documents approval as a 'genuine researcher' under 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.
- 7.3 Fees may be levied by QHFSS to recover costs associated with ethical review and monitoring of research projects from applicants external to QH.
- 7.4 All costs associated with seeking coronial and next of kin consent and retention of autopsy tissues for approved projects are required to be funded by the relevant project.
- 7.5 For further information please refer to Research Involving Material from Coroners' Autopsies: Advice to ethics committees and researchers on the Forensic & Scientific Human Ethics Committee 'Site requirements' webpage:
http://www.health.qld.gov.au/ohmr/html/regu/hrec_contacts.asp

SECTION 7: HREC MONITORING OF RESEARCH GIVEN INSTITUTIONAL AUTHORISATION

General Policy on monitoring of research

- 7.1 Research should normally commence within 12 months of the date of ethical approval. For clinical trials, the start date refers to the first point of recruitment i.e. the date when the advertising or screening for participants begins. The finish date refers to when no further contact with any data source is foreseen including the data analysis and reporting period. For non clinical trials, the start date is from the date of District authorisation.
- 7.2 Should the study not commence within 12 months, the Principal Investigator 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
- 7.3 Should the project not commence within 24 months, the matter should be discussed at a meeting of the HREC. At the discretion of the HREC, the approved ethical decision may be suspended and the Principal Investigator required to submit a new application once the problems relating to the delay of the study have been fully addressed.
- 7.4 To allow monitoring to occur, the HREC Chairperson or delegate may decide to allow other persons access to HREC application 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. This may include random inspections of research sites, data, or consent documentation and interviews with research participants or other forms of feedback from them.

Duration of a approved ethical decision

- 7.5 The approved ethical decision of the main HREC applies for the expected duration of the research as specified in the application form, except where action is taken to suspend or terminate the decision. Where the sponsor or Principal Investigator proposes to extend the duration of the study, for example to allow more time for recruitment of participants, this should be submitted for review by the main HREC

Progress reports

- 7.6 Progress reports on all research given an approved decision should be submitted to the HREC at least annually, or more frequently if the level of risk is assessed by the HREC to so indicate. The first Annual Report should be submitted 12 months after the date on which ethical approval was given.
- 7.7 When giving an approved decision on an application, the HREC may require as an approval condition that more regular reports should be submitted, or it may request an additional progress report at any time. Reporting time frames should be recorded in AU – RED.
- 7.8 Progress reports should be in the format prescribed. Reports must be submitted by the Principal Investigator (or CPI for multi-centre studies) and signed.
- 7.9 In the case of company sponsored clinical trial, the annual report should be accompanied by the reporting letter from the Data Safety Monitoring Board appointed by the company to monitor the trial.
- 7.10 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.
- 7.11 Progress reports should be added to the agenda and reviewed by the committee.
- 7.12 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 Chairperson should consider what further action should be taken. Where it is proposed to suspend the HREC's approved ethical decision, the matter should be considered at a meeting of the HREC.
- 7.13 The progress report should be uploaded onto the online forms by the researcher.

AU – RED ALERT

SF17: Progress Report Form

SL15: Reminder for Progress Report

SL16: Acknowledgement of Progress Report

Final Reports

- 7.14 A final report on all research given District authorisation should be submitted to the HREC at completion of the research and should include a copy of the final published results.
- 7.15 The final report should be uploaded onto the online forms by the researcher.
- 7.16 Final reports should be added to the agenda and reviewed by the committee. The study status should be updated in AU – RED.

AU – RED ALERT

SF18: Research Final Report Form

SL17: Acknowledgement of Final Report without Results

SL18: Acknowledgement of Final Results

Urgent Safety Measures

- 7.17 The Coordinating Principal Investigator, or a Site Principal Investigator 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. The HREC must be notified immediately and in any event within 3 days that such measures have been taken. The notice should set out the reasons for the urgent safety measures and the plan for further action. QH policy is that these requirements should apply to all research with an approved decision from a HREC and authorisation by the District CEO or Delegate of the QH District.
- 7.18 Notifications of urgent safety measures should be reviewed at a 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. Where any concern arises about the safety or welfare of participants or the conduct of the research, the HREC should address these with the Principal Investigator in writing.

Early Termination of Study by the Principal Investigator

- 7.19 Where a research project is terminated or suspended by the Principal Investigator prematurely, the HREC must be promptly informed and provided with a detailed written explanation of the circumstances, having regard to the ongoing safety and welfare of any research participants who may be receiving study treatment.
- 7.20 Notification of early termination of a study should be added to the agenda and reviewed by the full Committee.
- 7.21 The study status on AU – RED should be updated accordingly.

Suspension or Withdrawal of HREC Approval

- 7.22 The HREC may suspend or withdraw its ethical approval 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.
- 7.23 Where the HREC considers it appropriate that the adverse event/s and/or monitoring reports requires the immediate suspension or discontinuation of the ethical approval of the research project, the HREC should immediately notify the Coordinating Principal Investigator (or Site Principal Investigator for single site studies).
- 7.24 An Investigator cannot continue with the research if ethical approval has been suspended or withdrawn and must comply with any special conditions imposed by the HREC or district/site Research Governance Office/r.

AU – RED ALERT

SL19: Suspension/Withdrawal of HREC approval for Research Project

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

- 7.25 Where the QH District CEO or Delegate is satisfied that circumstances have arisen such that it is no longer appropriate to conduct a research project at the District/Site, the District may suspend or withdraw its authorisation to conduct the research at the site.

- 7.26 In such circumstances, the site RGO is required to immediately notify the Coordinating Principal Investigator (or Site Principal Investigator for single site studies).
- 7.27 This notification must be confirmed in writing within three working days.
- 7.28 An Investigator cannot continue with the research if the District CEO or Delegate has suspended or withdrawn authorisation for the research to be conducted at the site.
- 7.29 Where there is suspension or withdrawal of research authorisation by the District/Site RGO, the District CEO or Delegate may be required to consult with the HREC to consider any safety aspects for research participants that may be involved in the research at the time of suspension or withdrawal of District authorisation.

HRECs and Adverse Event Reporting in Australian for Clinical Trials

- 7.30 Institutions and HRECs have important responsibilities in relation to reports of serious adverse events or serious adverse reactions occurring in clinical trials for which institutions are responsible and that HRECs have reviewed and given ethical approval.
- 7.31 The responsibility of HRECs, and the institutions they advise, is to protect the safety of participants in clinical trials. In order to effectively undertake this responsibility, HRECs need to receive sufficient reliable information about the implications of adverse events or reactions.
- 7.32 The investigator/researcher must capture and report AEs, including SAEs, which occur at their site to the sponsor in accordance with the study protocol. The investigator/researcher must report all SAEs to the sponsor immediately (within 24 hours of finding out about the event) in accordance with the study protocol and GCP guidelines as adopted by the TGA. The following table is a summary of requirements for adverse event reporting to HRECs by Investigators adapted from the Australian Health Ethics Committee (AHEC) Position Statement: Monitoring and reporting of safety for clinical trials involving therapeutic products MAY 2009 for reporting requirements.
- http://www.nhmrc.gov.au/_files_nhmrc/file/health_ethics/hreCs/reference/090609_nhmrc_position_statement.pdf

For every trial, an investigator /researcher must provide:

<p>In accordance with individual institutional requirements</p> <p><i>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</i></p>	<ul style="list-style-type: none"> • to institution (or HREC as specified by institution) — AEs or SAEs occurring at their site(s)
<p>In a prompt manner</p>	<ul style="list-style-type: none"> • to HREC responsible for trial — information which materially impacts the continued ethical acceptability of the trial or — information that requires, or indicates the need for, a change to the trial protocol, including changed safety monitoring in the view of the investigator or sponsor.
<p>At least six-monthly</p>	<ul style="list-style-type: none"> • to HREC responsible for trial — 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.
<p>At least annually</p>	<ul style="list-style-type: none"> • to HREC responsible for trial — an updated Investigator Brochure, or — an EU ASR (or similar format report), or — current, approved Product Information (PI), if appropriate (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 National Statement and Good Clinical Practice (GCP) as adopted by the Therapeutic Goods Administration (TGA)

Fully Sponsored Pharmaceutical or similar Trials:

- 7.33 The reviewing HREC should be provided, by the CPI, with a copy of the SAE notification that is sent by the site to the sponsor as soon as possible and within a one month maximum time lapse
- 7.34 If the event is serious and unexpected and may affect other participants on the trial, the reviewing HREC and Institution (e.g RGO; institutional safety monitoring committee) must receive immediate notification (that is, within 24 hours of the investigator becoming aware of the event)
- 7.35 For all studies the CPI / PI must notify the reviewing HREC (e.g by cover letter / reporting template) that the report has been reviewed by the CPI / PI and documents what, if any, changes have been determined for the study.
- 7.36 If any changes to the study are required, these must be submitted as an amendment.
- 7.37 All reports, including the cover letter / reporting template, should be uploaded onto the online forms by the researcher. Researchers should request sponsors submit the reports in an electronic version as well as hard copy version, if requested by the reviewing HREC, in order for the researcher to be able to upload the reports onto the online forms.

Non Sponsored Trials:

- 7.38 Non sponsored trials with only a local DSM Committee are required to immediately provide notification to the HREC within 24 hours of the investigator becoming aware of the event. If it is considered that the SAE is related to the study, immediate notification to the reviewing HREC and institution administration (e.g RGO; institutional safety monitoring committee) is required.
- 7.39 For all studies the CPI / PI must notify the reviewing HREC (e.g by cover letter / reporting template) that the report has been reviewed by the CPI / PI and documents what, if any, changes have been determined for the study.
- 7.40 If any changes to the study are required, these must be submitted as an amendment.
- 7.41 All reports, including the cover letter / reporting template, should be uploaded onto the online forms by the researcher.

SF19: SAE Report – Local

SF20: SAE Report – External

Tracking of Medical Devices:

- 7.42 Tracking of medical devices is as per the TGA requirements and Australian Medical Devices Guidelines.
- 7.43 Medical Device TGA SAE Forms and guidelines:
http://www.tga.gov.au/docs/pdf/forms/iris_mdir03b.pdf and
http://www.tga.gov.au/docs/pdf/forms/iris_udir03c.pdf
<http://www.tga.gov.au/docs/pdf/devguid11.pdf>
- 7.44 Device identifiers are placed into patients medical notes and manufacturers are required to maintain a tracking system

SECTION 8: FEES FOR HREC REVIEW OF RESEARCH APPLICATIONS

Schedule of Fees

8.1 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.

SF21: Fees for review of commercially sponsored research by Human Research Ethics Committees and Governance Review (Site-specific Assessment)

Background

8.2 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 HRECs.

- 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;
- the potential to prevent ethical consideration of research applications due to inability to pay, e.g. students.

8.3 Queensland Health (QH), whilst acknowledging these concerns, has implemented a policy of charging for HREC review, independent expert review and site-specific assessments of research applications (unless exempt). These fees should be applied consistently throughout Queensland by QH HRECs.

Payment of Fees

8.4 It is the responsibility of the researcher to provide the HREC / RGO with details of the sponsor organisation contact to whom the Invoice will be sent.

8.5 Institutions may elect for Invoices to be paid prior to dispatch of approval letters.

8.6 If cheques are received by the HREC / RGO they should be promptly forwarded to the Finance Department in line with local administrative requirements and recorded on AU-RED and the Money Received Register

Exemptions from Fees

8.7 Institutions may, under the following circumstances, grant partial or complete exemption from the above fees under the following categories:

- Bona fide students' applications as part of the requirements for a higher degree
- Investigator-initiated studies within the institution, without external funding
- Applications funded by not-for-profit organisations, e.g. NHMRC, Queensland Cancer Fund and collaborative research groups such as TROG, ALLG and AKTN

8.8 There is no fee for review of Investigator Brochures or Participant Information Sheets and Consent Forms.

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

8.9 The QH 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, eg. minutes
- Liaising with other sites and reporting to AHEC, QH District Executive and QH Corporate Office
- Payments to external scientific reviewers and others as necessary
- Advising and providing ethical education and training to researchers and QH HREC members and administration
- Maintaining the QH Research Management IT System
- 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 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

SECTION 9: PROCESS FOR APPOINTING HREC MEMBERS

- 9.1 The institution is to recruit members for an HREC using open and transparent processes. No members will adjudicate on applications in which they have an interest as researcher or supervisor or funding body.
- 9.2 Membership must reflect the National Statement minimum membership requirements as listed in 5.1.29. Members are to be appointed for their expertise and knowledge and not in a representative capacity.
- 9.3 Members are not to be appointed in more than one of the categories listed in 5.1.30 of the National Statement. A HREC may establish a pool of inducted members in each category (refer to Co-opted Members)
- 9.4 Institutions should review appointments to the HREC at least every three years.

SF22: Membership Selection Criteria

- 9.5 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.

SF23: Expression of Interest for HREC/SSC Members

SL22: Letter of Appointment for HREC/SSC Members

SL24: Acknowledgement of Obligations/Acceptance of Appointment

SF25: Agreement to enter personal contact details on

INFONETICA AU – RED for HREC Members

- 9.6 Members should undertake appropriate induction. This includes providing a copy of the National Statement, Code and HREC Terms of Reference and HREC meeting dates. Induction should also include mentoring by a current HREC member and continuing education (refer to Section 13: Continuing Education for HREC Members and Administrators).

SF26: HREC TOR

9.7 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

SF10: Composition of HREC

SECTION 10: HANDLING COMPLAINTS

General Policy

- 10.1 Research complaints can be about the conduct of research including the conduct of the researchers, and / or about the conduct of the HREC.
- 10.2 NHMRC 'The Australian Code for the Responsible Conduct of Research' 2007 (The Code) includes a description of 'research misconduct' and includes processes for Institutions to handle these complaints. The site/district should ensure that all personnel are aware of their responsibilities.
- 10.3 Sites/districts must make public the process for receiving and resolving allegations of research misconduct. This should be consistent with the Code, the QH General Principles for Handling Research Complaints and QH – Complaints Process for Research Misconduct.
- 10.4 Handling of research complaints, including misconduct, is the responsibility of the authorising HREC's institution.

SF4: General Principles for Handling Research Complaints

Complaints concerning the conduct of a project

- 10.5 As per The Code an institution will nominate 'advisers in research integrity' to advise possible complainants about research conduct issues and explain the options open to persons considering, making, or having made an allegation.
- 10.6 As per The Code the institution will nominate a 'designated person' for handling research complaints, including research misconduct.
- 10.7 Any concern, allegations or complaints about the conduct of a project must be reported, in the first instance, to the authorising HREC institution's designated person for handling research complaints, including research misconduct.
- 10.8 Any complaints received must also be forwarded to the secretariat of the HREC who will enter the complaint details on AU RED and to the local site RGO where the complaint applies.
- 10.9 Initially, complaints should be forwarded by the designated person to the relevant department to be dealt with at departmental level.

- 10.10 The departmental decision will be reported back to the 'designated person' and the HREC secretariat.
- 10.11 The 'designated person' will review the departmental decision and make a recommendation to the HREC on the appropriate course of action.
- 10.12 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 Chief Executive Officer (CEO) or his/her nominee for appeal.
- 10.13 For allegations not resolved at departmental level and appeals, the institution's CEO or his/her nominee 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.
- 10.14 The decision of the investigating committee will be final.
- 10.15 Participant Information Sheet and Consent forms must include contact details to allow such complaints to be made.
- 10.16 All complaints will be acknowledged within seven (7) days.
- 10.17 The complainant will be advised of the decision within 30 days.

Complaints concerning the HREC's review process including the HREC's rejection of an application

- 10.18 Any concern or complaint about the HREC's review process should be directed to the attention of the Chairperson of the HREC, detailing it in writing.
- 10.19 The Chairperson will notify the CEO of any complaints received by him/her, as soon as possible. The CEO will inform the Chairperson of any complaints received by him/her as soon as possible.
- 10.20 The Chairperson will investigate the complaint and its validity, and make a recommendation to the HREC on the appropriate course of action.
- 10.21 If the complainant is not satisfied with the outcome of the Chairperson's investigation, then he/she can refer the complaint to the CEO, or his/her nominee, or request the Chairperson to do so.
- 10.22 The Chairperson will provide to the Chief Executive all relevant information about the complaint/concern.
- 10.23 The Chief Executive will determine whether there is to be a further investigation of the complaint.
- 10.24 If it is decided there is to be a further investigation, then the CEO will convene an investigating committee to review the complaint, ensuring that both the complainant

and the HREC are afforded the opportunity to make submissions. 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.

10.25 The decision of the investigating committee will be final

SECTION 11: REIMBURSEMENT OF EXPENSES FOR HREC MEMBERS

- 11.1 It is the responsibility of the HREC Administrator to ensure that HREC members' legitimate expenses are reimbursed without delay.
- 11.2 Reasonable expenses incurred travelling to and from HREC meetings will be reimbursed.
- 11.3 A receipt is required.
- 11.4 Complete Petty Cash Voucher.
- 11.5 Complete Staff Expense Claim.
- 11.6 A small gift of appreciation, not above the QH reportable threshold, may be made to HREC members each year in recognition of the very substantial time commitment and intellectual input they make to Queensland Health. Refer to FMPM Circular No. 4/2010 Giving & receiving of Gifts & benefits for advice:

http://qheps.health.qld.gov.au/finance/sfs/fmpm/documents/circulars/gifts_policy.pdf

SECTION 12: EDUCATION AND TRAINING OF HREC MEMBERS AND ADMINISTRATORS

12.1 ESSENTIAL READING:

- 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 of the Privacy Act.
- Guidelines under Section 95a of the Privacy Act.
- Queensland Health Information Standard 42A.
- Queensland Health Research Management Policy December 2007 or any subsequent revised policy document.
- Financial Standard 1997
- Coroners Act 2003, s.53

12.2 Training and education on ethical review should occur at least biannually.

12.3 Members and staff wishing to attend should complete an Application for Conference and Study Leave. The Administrator will oversee all applications, i.e. approval by authorised persons, travel arrangements through the Travel Hub, payment through Finance Department.

12.4 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.

12.5 It is the responsibility of the Administrator to maintain a register of all training provided to committee members.

SECTION 13: STORAGE AND RETENTION OF HREC RECORDS AND DOCUMENTATION

- 13.1 The Queensland Health Strategic Records Management Team have advised that until such a time that the retention disposal schedule has been approved by Queensland State Archives, that all HREC records should be held by sites indefinitely.
- 13.2 Further information can be obtained from the Queensland Health Strategic Records Management Team on 3239 0928.

APPENDIX 1: STANDARD LETTERS AND FORMS

STANDARD LETTERS:

Receipt of Application

SL1: Acknowledgement of receipt of a valid application

SL2: Acknowledgement of receipt of invalid application

SL3: Acknowledgement of withdrawal of application

HREC Meeting

SL4: Acknowledgement of Application and invitation to a meeting

SL5: Proposal not requiring review by HREC

Review by HREC and Scientific Sub-committee or PEER

SL6: Approval of Application

SL7: Request for further information or clarification in order to reach a final decision

SL8: Advice to Researcher/s regarding delay in HREC decision pending consultation with Scientific Subcommittee/Expert Reviewer

SL9: HREC Request for QH External Expert Review of Research Proposal

SL11: Unapproved HREC decision following SSC/EER review

SL12: Request for further information - response not approved

Response to Post Authorisation Amendments

SL20: Acknowledgement of receipt of a valid HREC amendment application

SL21: Acknowledgement of receipt of invalid HREC amendment application

SL13: Approved decision of post authorisation amendment

SL14: Unapproved decision of post authorisation amendment with options for further review

HREC Reporting

SL15: Reminder for Progress Report

SL16: Acknowledgement of Progress Report

SL17: Acknowledgement of Final Report without Results

SL18: Acknowledgement of Final Results

SL19: Suspension/Withdrawal of HREC approval for a Research Project

Process for Appointing Committee Members

SL22: Appointment letter for HREC/SSC Member

SL24: Acknowledgement of acceptance of HREC position

Complaints

SL25: Acknowledgement receipt of complaint

SL26: Acknowledgment resolution of complaint

SL27: Acknowledgement of adverse event report

STANDARD FORMS:

Receipt of Application

SF1: HREC Submission Checklist for Researchers – New Application

HREC Meeting

SF2: Research Ethics Agenda – Generated by AU – RED

SF3: HREC Cover Sheet for New Applications

Review by HREC and Scientific Sub-committee or PEER

SF4: Agreement for the conduct of Expert Review

SF5: Queensland Health External Expert Research Proposal Review Report Form

SF6: VIMA Expert Review Proforma: Pharmacology and Toxicology – on line form

SF7: VIMA Expert Review Proforma: Formulation/Manufacturing– on line form

SF8: VIMA Expert Review Proforma: Immunology– on line form

SF9: HREC Minutes – Generated by AU – RED

SF10: Composition of HREC

SF11: Research Commencement Form

SF12: NHMRC Requirements

Review of Research involving only Low Risk or Negligible Risk

SF13: Checklist and application for Exempt and Low Risk Research – online form

HREC Reporting

SF17: Annual/Progress Report Form

SF18: Research Final Report Form

SF19: SAE Report – Local

SF20: SAE Report – External

Finance Related Documents

SF21: Fees for review of commercially sponsored research by Human Research Ethics
Committees and Governance Review (Site Specific Assessment)

Process for Appointing Committee Members

SF22: Process for appointing HREC members

SF23: Expression of Interest for HREC/SSC Members

SF25: Agreement to Store Personal Contact Information on Infonetica AU – RED for HREC/SSC Members

SF26: HREC Terms of Reference

Handling Complaints

SF27: General Principles of Handling Research Complaints

SF28: Complaints Process – HRECs and Research misconduct

Student Related Forms

SF29: Internet Student Orientation Package Checklist –Example only

SL1: Acknowledgement of receipt of a valid application

Office of the Human Research Ethics Committee

[date]

Enquiries to:

Phone:

Fax:

HREC Ref:

E-mail

[Name and address of investigator]

Dear [name]

HREC Reference number: [HREC Reference]

Project title: [Full Title]

Protocol number: [Where applicable]

Thank you for submitting the above research project to the [HREC Name] Human Research Ethics Committee for ethical and scientific review, which was received on [HREC Application Received Date].

Your project has been assigned the Reference number:[HREC Reference].

This number must be quoted in all correspondence to this HREC.

Detailed information about the Queensland Health process for submission and authorisation of research can be obtained from the Research Ethics and Governance Unit website:

http://www.health.qld.gov.au/ohmr/html/regu/regu_home.asp.

You may wish to monitor the progress of your research proposal review. To do so, go to the login to your account at www.ethicsform.org/au , and select the tab 'monitor'. This will provide you with an update on your proposal.

Should you require any additional information, please contact the HREC [Co-ordinator Name] on [Phone] or [Email].

Yours sincerely

Coordinator

Human Research Ethics Committee

c.c. [name and address of research assistant if applicable]

SL2: Acknowledgement of receipt of invalid application

Office of the Human Research Ethics Committee

[date]

Enquiries to:

Phone:

Fax:

HREC Ref.:

E-mail

[Name and address of investigator]

Dear [name]

HREC Reference number: [HREC Reference]

Project Title: [Full Title]

Protocol number: [Where applicable]

Thank you for submitting the above research project to the [HREC Name] Human Research Ethics Committee (HREC) for ethical and scientific review, which was received on [HREC Application Received Date].

Your project has been assigned the Reference number: [HREC Reference]

This number must be quoted in all correspondence to this HREC.

Unfortunately, the application is not valid, for the following reasons:

[List reasons entered on AU-RED Validation Screen]

[Enter any other discrepancies].

You are welcome to re-submit the application, taking into account the above points. The 60 day time frame will not commence until a valid application has been received.

Detailed information about the Queensland Health process for submission and authorisation of research can be obtained from the Research Ethics and Governance Unit website:

http://www.health.qld.gov.au/ohmr/html/regu/regu_home.asp

Should you require any additional information, please contact the HREC Co-ordinator, [Co-ordinator Name] on [Phone] or [Email].

Yours sincerely

Coordinator

Human Research Ethics Committee

c.c. [name and address of research assistant if applicable]

SL3: Acknowledgement of withdrawal of Application

Office of the Human Research Ethics Committee

[date]

[Name and address of investigator]

Dear [name]

HREC Reference Number: [HREC Reference]

Project title: [Full Title]

Protocol number: [Where applicable]

Enquiries to:

Phone:

Fax:

HREC Ref:

E-mail

The above research project was submitted to the [HREC Name] Human Research Ethics Committee (HREC) for ethical and scientific review on the [HREC Application Received Date].

I wish to acknowledge that the application has been withdrawn by the [Researcher/HREC Co-ordinator] on the [Date].

The application has been registered as withdrawn on the Research Ethics Database and if you wish to re-submit the application, it will be treated as a new submission.

Detailed information about the Queensland Health process for submission and authorisation of research can be obtained from the Research Ethics and Governance Unit website:

http://www.health.qld.gov.au/ohmr/html/requ/regu_home.asp

Should you require any additional information, please contact the HREC Co-ordinator, [Co-ordinator Name] on [Phone] or [Email].

Yours sincerely

Coordinator

Human Research Ethics Committee

c.c. [name and address of research assistant if applicable]

SL4: Acknowledgement of Application and invitation to a Meeting

Office of the Human Research Ethics Committee

[date]

[Name and address of investigator]

Dear [name]

HREC Reference Number: [HREC Reference]

Project title: [Full Title]

Protocol number: [Where applicable]

Enquiries to:

Phone:

Fax:

HREC Ref.:

E-mail

Thank you for submitting the above research project to the [HREC Name] Human Research Ethics Committee (HREC) for ethical and scientific review. The HREC will review your proposal at its meeting to be held on [Meeting Date].

Your project has been assigned the Reference number: [HREC Reference]

This number must be quoted in all correspondence to the HREC.

[Delete the following paragraphs if not applicable]

The HREC would like to invite you to the meeting to further discuss aspects of your proposal and to assist them in considering the scientific and ethical aspects of the research. Please contact the HREC Co-ordinator to confirm your availability and arrange a suitable time to attend the meeting.

After the meeting, you will be notified in writing of the outcome of the HREC's review of your proposal within 10 working days of the meeting at which the proposal is considered, unless otherwise notified.

You will be notified in writing of the outcome of the HREC's review of your proposal within 10 working days of the meeting at which the proposal is considered, unless otherwise notified.

Please note, once you have been formally notified of the HREC's decision, a completed application for site-specific assessment must also be submitted to the Research Governance

Office/r at this site once. Researchers are encouraged to begin preparing site-specific assessment applications as soon as possible. For further information on site-specific assessments, please contact the site Research Governance Office/r on Insert Name and Contact details.

You cannot commence this project until the District CEO or Delegate has granted authorisation.

Detailed information about the Queensland Health process for submission and authorisation of research can be obtained from the Research Ethics and Governance Unit website:

http://www.health.qld.gov.au/ohmr/html/requ/requ_home.asp

Should you require any additional information, please contact the HREC Co-ordinator, [Co-ordinator Name] on [Phone] or [Email].

Yours sincerely

Coordinator

Human Research Ethics Committee

c.c. [name and address of research assistant if applicable]

SL5: Proposal not requiring review by HREC

Office of the Human Research Ethics Committee

[date]

[Name and address of investigator]

Enquiries to:

Phone:

Fax:

HREC Ref:

E-mail

Dear [name]

HREC Reference Number: [HREC Reference]

Proposal title: Full Title

Should you require any additional information, please contact the HREC Co-ordinator, Name on Phone Number or Email

The above proposal was submitted to the [HREC Name] Human Research Ethics Committee (HREC) for advice/opinion regarding ethical and scientific review on the [HREC Application Received Date].

I wish to acknowledge that the proposal does not require full HREC review on the basis of [reason].

Yours sincerely

Coordinator

Human Research Ethics Committee

c.c. [name and address of research assistant if applicable]

SL6: Approval of Protocol

Office of the Human Research Ethics Committee

[date]

Enquiries to:

Phone: [phone]

Fax: [Fax]

Our Ref: [HREC Reference]

E-mail [Email]

[CPI Name]

[CPI Address]

Dear [CPI Name]

HREC Reference number: [HREC Reference]

Project title: [Full Title]

Protocol number: [Where applicable]

Thank you for submitting the above project for ethical and scientific review. This project was first considered by the [HREC Name] Human Research Ethics Committee (HREC) held on [Meeting Date].

This HREC is constituted and operates in accordance with the National Health and Medical Research Council's (NHMRC) *National Statement on Ethical Conduct in Human Research (2007)*, *NHMRC and Universities Australia Australian Code for the Responsible Conduct of Research (2007)* and the *CPMP/ICH Note for Guidance on Good Clinical Practice*. Attached is the HREC Composition with specialty and affiliation with the Hospital (Attachment I).

[Following consultation with one or more expert reviewers with qualifications or knowledge in disciplines relevant to your research proposal,] I am pleased to advise that the Human Research Ethics Committee has granted approval of this research project. The documents reviewed and approved include:

Document	Version	Date
[this will populate with details of all reviewable docs from Application Checklist]		

Please note the following conditions of approval:

*Standard Operating Procedures for Queensland Health HRECs
Developed by the Research Ethics & Governance Unit
Version 3 – May 2010
For use from 1 July 2010.*

Insert any special conditions of approval imposed by the HREC.

The Principal Investigator will immediately report anything which might warrant review of ethical approval of the project in the specified format, including:

Unforeseen events that might affect continued ethical acceptability of the project.

Serious Adverse Events must be notified to the Committee as soon as possible. In addition the Investigator must provide a summary of the adverse events, in the specified format, including a comment as to suspected causality and whether changes are required to the Patient Information and Consent Form. In the case of Serious Adverse Events occurring at the local site, a full report is required from the Principal Investigator, including duration of treatment and outcome of event.

Amendments to the research project which may affect the ongoing ethical acceptability of a project must be submitted to the HREC for review. Major amendments should be reflected in a revised online NEAF (accompanied by all relevant updated documentation and a cover letter from the principal investigator, providing a brief description of the changes, the rationale for the changes, and their implications for the ongoing conduct of the study). Hard copies of the revised NEAF, the cover letter and all relevant updated documents with tracked changes must also be submitted to the HREC coordinator as per standard HREC SOP. Further advice on submitting amendments is available from http://www.health.qld.gov.au/ohmr/html/regu/regu_home.asp

Amendments to the research project which only affect the ongoing site acceptability of the project are not required to be submitted to the HREC for review. These amendment requests should be submitted directly to the Research Governance Office/r (by-passing the HREC).

Proposed amendments to the research project which may affect both the ethical acceptability and site suitability of the project must be submitted firstly the HREC for review and, once HREC approval has been granted, then submitted to the RGO.

Amendments which do not affect either the ethical acceptability or site acceptability of the project (e.g. typographical errors) should be submitted in hard copy to the HREC coordinator. These should include a cover letter from the principal investigator providing a brief description of the changes and the rationale for the changes, and accompanied by all relevant updated documents with tracked changes.

The HREC will be notified, giving reasons, if the project is discontinued at a site before the expected date of completion.

The Principal Investigator will provide an annual report to the HREC and at completion of the study in the specified format.

The District administration and the Human Research Ethics Committee may inquire into the conduct of any research or purported research, whether approved or not and regardless of the source of funding, being conducted on hospital premises or claiming any association with the Hospital; or which the Committee has approved if conducted outside [name] Hospital Health Service District.

HREC approval is valid for [Insert Length of HREC Approval] from the date of this letter.

Should you have any queries about the HREC's consideration of your project please contact [Name and Contact details of HREC Executive Officer or Chairperson]. The HREC terms of Reference, Standard Operating Procedures, membership and standard forms are available from http://www.health.qld.gov.au/ohmr/html/regu/regu_home.asp

You are reminded that this letter constitutes ethical approval only. You must not commence this research project at a site until separate authorisation from the District CEO or Delegate of that site has been obtained.

A copy of this approval must be submitted to the District Research Governance Officer/Delegated Personnel with a completed Site Specific Assessment (SSA) Form for authorisation from the CEO or Delegate to conduct this research at the [name] District.

Once authorisation to conduct the research has been granted, please complete the Commencement Form (Attachment II) and return to the office of the Human Research Ethics Committee.

The HREC wishes you every success in your research.

Yours faithfully

for

[Chairperson Name]

CHAIRPERSON

HUMAN RESEARCH ETHICS COMMITTEE

[name] **DISTRICT**

c.c. [name and address of research assistant/study coordinator if applicable]

SL7: Request for further information or clarification in order to reach a final opinion

Office of the Human Research Ethics Committee

[date]

Enquiries to:

Phone:

Fax:

Our Ref:

E-mail

[Name and address of Investigator]

Dear [name]

HREC Reference number:

Project title:

Protocol Number:

Thank you for submitting the above project, which was first considered by the [HREC Name] Human Research Ethics Committee (HREC) at its meeting held on [Meeting Date].

In order to make a determination of the ethical and scientific acceptability of your project, please respond to the following request for additional information/clarification or modification:

[Enter text from 'Request for Further information' test box on AU-RED decision page if available]

[List each request separately. Each request must clearly articulate the reasons for this determination and clearly set out the information that is required, relying on the relevant paragraphs of the National Statement, relevant legislation or other applicable guidelines.]

Please refer to paragraph [insert relevant paragraph/s of the National Statement, relevant legislation or other applicable guidelines].

In order to facilitate the HREC's consideration of your project, please provide the requested information as soon as possible. Your response may be emailed to the HREC Co-ordinator however this should be accompanied by a hard copy [or insert relevant procedure].

Please note that if the requested information is not received within 3 months or two meetings (whichever occurs sooner), the project will be dismissed and you will be required to re-submit the project at a later date.

Should you have any queries about your project please contact the HREC Co-ordinator, [Co-ordinator Name] on [Phone] or [Email].

Yours sincerely

Coordinator

Human Research Ethics Committee

c.c. [name and address of research assistant if applicable]

SL8: Advice to Researcher/s Regarding delay in HREC decision pending consultation with Scientific Subcommittee/Expert Reviewer

Office of the Human Research Ethics Committee

[date]

Enquiries to:

Phone:

Fax:

HREC Ref:

E-mail

[Name and address of Investigator]

Dear [Name]

HREC Reference number: [HREC Reference]

Project title: [Full Title]

Protocol number: [Where applicable]

At a meeting of the [HREC name] Human Research Ethics Committee held on [Meeting Date], the Committee reviewed the above Protocol.

The [HREC name] Human Research Ethics Committee is duly constituted, and operates and complies with the National Health and Medical Research Council's 'National Statement on Ethical Conduct in Human Research' (2007) and the NHMRC and Universities Australia Australian Code for the Responsible Conduct of Research (2007).

In accordance with this Statement, the [HREC name] Hospital Human Research Ethics Committee has decided to request the advice of one or more expert reviewers with appropriate qualifications or knowledge in disciplines relevant to your research proposal. Following receipt of this advice, the Committee will re-examine the Research Protocol.

At present, it is anticipated that this Protocol will be reviewed at the meeting of the [HREC name] Human Research Ethics Committee to be held on [Meeting Date].

You will be notified of the Committee's decision regarding the protocol as soon as possible after the meeting. If you have any questions in the interim, please do not hesitate to contact me.

Yours sincerely

Coordinator

Human Research Ethics Committee

c.c. [name and address of Research Assistant if applicable]

SL9: HREC Request for QH External Expert Review of Research Proposal

(SF4, SF5 & SF9 should be included with this correspondence)

Enquiries to: HREC Administrator
Telephone: Tel No.
Facsimile: Fax No.
Email:
HREC Ref:

[Name and address of investigator]

Dear [name]

HREC Reference Number: [HREC Reference]

Project title: [Full Title]

Protocol number: [Where applicable]

We are a duly constituted Human Research Ethics Committee based at the Queensland [District Name] and we are currently reviewing a Research Proposal with particular relevance to your area of expertise.

We are writing to request your assistance in reviewing the attached research proposal. If you are unable to assist us in this instance, please indicate this on the attached cover sheet and return the documents intact to this committee as soon as possible.

If you agree to conduct this review, could you please refer to the Research Proposal documents and the Expert Reviewer Suggested Research Review Questions. This document contains a range of questions that may assist you in addressing the validity and quality of the proposal.

On completion of your review of this research proposal, may we request that you forward your report and research proposal to:

..... by...../...../.....
[HREC Co-ordinator name] [Date]

The HREC Administrator,
c/o HREC, District
[Postal Address]

Should you have difficulty meeting this deadline, please do not hesitate to contact the HREC Co-ordinator to discuss alternative options. Re-imbursement for postage and other relevant costs is also available from the HREC Co-ordinator.

Thank you in advance for your participation in the review process.

Yours sincerely,

Co-ordinator
Human Research Ethics Committee

SL11: Unapproved decision on Protocol given by HREC following advice from Scientific Sub Committee/ Expert Reviewer

Office of the Human Research Ethics Committee

[date]

Enquiries to:

Phone:

Fax:

HREC Ref.:

E-mail

[Name and address of Investigator]

Dear [name]

HREC Reference number: [HREC Reference]

Project title: [Full Title]

Protocol number: [Where applicable]

Thank you for submitting the above project which was first considered by the [HREC name] Human Research Ethics Committee (HREC) at its meeting held on [Meeting Date].

The HREC is constituted and operates in accordance with the National Health Council's (NHMRC) *National Statement on Ethical Conduct Human Research (National Statement)*, *NHMRC and Universities Australia Australian Code for the Responsible Conduct of Research (2007)* and the *CPMP/ICH Note for Guidance on Good Clinical Practice*.

Following consultation with one or more expert reviewers with qualifications or knowledge in disciplines relevant to your research proposal, the HREC has decided not to approval your project for the following reasons:

[List each reason separately. Each reason must refer to the relevant paragraph/s of the National Statement, relevant legislation or other applicable guidelines].

Should you wish to discuss the HREC's review of your project, please contact the HREC [coordinator Name] on [Phone] or [Email].

Yours sincerely

Coordinator

Human Research Ethics Committee

c.c. [name and address of research assistant if applicable]

*Standard Operating Procedures for Queensland Health HRECs
Developed by the Research Ethics & Governance Unit
Version 3 – May 2010
For use from 1 July 2010.*

SL12: Request for further information - response not approved

Office of the Human Research Ethics Committee

[date]

[Name and address of investigator]

Enquiries to:

Phone:

Fax:

HREC Ref.:

E-mail

Dear [name]

HREC Reference Number: [HREC Reference]

Project title: [Full Title]

Protocol number: [Where applicable]

Thank you for submitting the above project which was first considered by the [HREC name] Human Research Ethics Committee (HREC) at its meeting held on [Meeting Date].

The HREC is constituted and operates in accordance with the National Health and Medical Research Council's (NHMRC) *National Statement on Ethical Conduct in Human Research (National Statement)*, *NHMRC and Universities Australia Australian Code for the Responsible Conduct of Research (2007)* and the *CPMP/ICH Note for Guidance on Good Clinical Practice*.

The HREC has decided not to approve your project for the following reasons:

[List each reason separately. Each reason must refer to the relevant paragraph/s of the National Statement, relevant legislation or other applicable guidelines].

Should you wish to discuss the HREC's review of your project, please contact the HREC Co-ordinator Name] on [Phone] or [Email].

Yours sincerely

Coordinator

Human Research Ethics Committee

c.c. [name and address of research assistant if applicable]

SL13: Approved decision of post authorisation amendments

Office of the Human Research Ethics Committee

[date]

Enquiries to:

Phone:

Fax:

HREC Ref:

E-mail

[Name and address of Investigator]

Dear [name]

HREC Reference number: [HREC Reference]

Project title: [Full Title]

Protocol number: [Where applicable]

Amendment number:

Amendment Date:

The above amendment was reviewed at the meeting of the [HREC, Chairperson, Sub-committee, Other] held on [Meeting Date].

I am pleased to advise that the amended documents reviewed and approved at the meeting were:

Document	Version	Date
Notification of amendment		
Eg: Drug data sheet		

The [HREC Name] HREC is constituted and operates in accordance with the National Health and Medical Research Council's *"National Statement on Ethical Conduct in Human Research (2007)"*, *NHMRC and Universities Australia Australian Code for the Responsible Conduct of Research (2007)* and the *"CPMP/ICH Note for Guidance on Good Clinical Practice"*.

A copy of this letter must be forwarded to the [District/Site Name] Research Governance Office/r.

It should be noted that all requirements of the original approval still apply.

Yours faithfully

Coordinator

Human Research Ethics Committee

c.c. [name and address of research assistant if applicable]

SL14: Unapproved decision of post authorisation amendments with options for further review

Office of the Human Research Ethics Committee

[date]

Enquiries to:

Phone:

Fax:

HREC Ref:

E-mail

[full name and address]

Dear [name]

HREC Reference number: [HREC Reference]

Project title: [Full Title]

Protocol number: [Where applicable]

Amendment number:

Amendment Date:

The above amendment was reviewed at the meeting of the [HREC, Chairperson, Sub-Committee, Other] held on [Meeting Date].

I regret to inform you that the amendment was not approved for the following reasons:

[list comments] (**Refer to relevant sections of the National Statement**)

The study should continue in accordance with the documentation previously approved by the Committee. You may modify or adapt the amendment, taking into account the concerns outlined above and re-submit the revised document(s).

A copy of this letter must be forwarded to the [District/Site name] Research Governance Office/r.

Should you require further clarification or information, please do not hesitate to contact me.

Yours sincerely

Coordinator

Human Research Ethics Committee

c.c. [name and address of research assistant if applicable]

SL15: Reminder for Progress Report

Office of the Human Research Ethics Committee

[date]

[Name and address of Investigator]

Enquiries to:

Phone:

Fax:

HREC Ref.:

E-mail

Dear [surname]

HREC Reference number: [HREC Reference]

Project title: [Full Title]

Protocol number: [Where applicable]

As you know, it is a condition of approval to conduct the above study that a progress report is forwarded to the Human Research Ethics Committee [Insert reporting time frame] and at the completion of the trial.

As we do not appear to have received a report within [Insert reporting time frame], I would be grateful if you could complete the attached Annual/Progress Report form or access this form from the Research Ethics and Governance Unit web site http://www.health.qld.gov.au/ohmr/html/regu/regu_home.asp, and return it to me at your earliest convenience.

I look forward to hearing from you. If I can be of any assistance, please do not hesitate to contact me.

Yours sincerely

Coordinator

Human Research Ethics Committee

c.c. [name and address of Research Assistant if applicable]

SL16: Acknowledgement of Progress Report

Office of the Human Research Ethics Committee

[date]

Enquiries to:

Phone:

Fax:

HREC Ref.:

E-mail

[Name and address of Investigator]

Dear [name]

HREC Reference number: [HREC Reference]

Project title: [Full Title]

Protocol number: [Where applicable]

Thank you for sending the progress report for the above study dated [Insert Date].

The report was reviewed at the meeting of the [HREC], [Chairperson], [Co-opted Chairperson], [Sub Committee], [Other] held on [date].

Yours sincerely

Coordinator

Human Research Ethics Committee

[insert: c.c. name and address of research assistant if applicable]

SL17: Acknowledgement of Final Report without Results

Office of the Human Research Committee

[date]

[Name and address of Investigator]

Enquiries to:

Phone:

Fax:

HREC Ref:

E-mail:

Dear [Name]

HREC Reference number: [HREC Reference]

Project title: [Full Title]

Protocol number: [Where applicable]

Thank you for sending the final report for the above study dated [Insert Date].

In accordance with HREC conditions of approval, we look forward to receiving the results so that we may close and archive our file.

Yours sincerely

Coordinator

Human Research Ethics Committee

[name and address of Research Assistant if applicable]

SL18: Acknowledgement of Final Results

Office of the Human Research Ethics Committee

[date]

[Name and address of Investigator]

Enquiries to:

Phone:

Fax:

HREC Ref:

E-mail:

Dear [Name]

HREC Reference number: [HREC Reference]

Project title: [Full Title]

Protocol number: [Where applicable]

Thank you for sending the final report for the above study dated [Insert Date].

The report was reviewed at the meeting of the [HREC], [Chairperson], [Co-opted Chairperson], [Sub-Committee], [Other] held on [Meeting Date].

The Committee would like to congratulate you and the investigating team on the successful outcome of the study.

We have now closed and archived our file.

Yours sincerely

Coordinator

Human Research Ethics Committee

c.c. [name and address of Research Assistant if applicable]

SL19: Suspension/Withdrawal of HREC approval for a Research Project.

Office of the Human Research Ethics Committee

[date]

[Name and address of investigator]

Enquiries to:

Phone:

Fax:

HREC Ref:

E-mail

Dear [name]

HREC Reference Number: [HREC Reference]

Project title: [Full Title]

Protocol number: [Where applicable]

The above project was approved by the [HREC Name] HREC at its meeting held on [Meeting Date].

This HREC is constituted and operates in accordance with the National Health and Medical Research Council's *National Statement on Ethical Conduct in Human Research (2007)* NHMRC and Universities Australia *Australian Code for the Responsible Conduct of Research (2007)* and the CPMP/ICH *Note for Guidance on Good Clinical Practice*.

The HREC has decided to [Choose Suspend/Withdraw] approval of your project for the following reasons:

[List each reason separately. Each reason must refer to the relevant paragraph/s of the *National Statement*, relevant legislation or other applicable guidelines].

[List any conditions that may restore HREC approval for the Research to proceed (if applicable)]

You are not authorised to continue with this research [HREC Reference number].

Should you wish to discuss the HREC's decision, please contact the HREC Co-ordinator, [Co-ordinator Name] on [Phone] or [Email].

Yours sincerely

Coordinator

Human Research Ethics Committee

c.c. [name and address of research assistant if applicable]

[Name and address of District/Site RGO]

SL20: Acknowledgement of receipt of a valid HREC amendment application

Office of the Human Research Ethics Committee

[date]

[CPI Name]

[CPI Address]

Enquiries to:

Phone: [phone]

Fax: [Fax]

Our Ref: [HREC Reference]

E-mail [Email]

Dear [CPI Name]

HREC Reference number: [HREC Reference]

Project title: [Full Title]

Protocol number: [Where applicable]

Thank you for submitting an amendment to the above research project, which was received on [HREC Application Received Date], to the [HREC Name] Human Research Ethics Committee for ethical and scientific review.

The HREC will review and make an assessment of the suitability of this amendment at its meeting to be held on [Meeting Date].

Should you require any additional information, please contact the HREC Co-ordinator, [Co-ordinator Name] on [Phone] or [Email].

Yours sincerely

Co-ordinator

Human Research Ethics Committee

c.c. [name and address of research assistant if applicable]

SL21: Acknowledgement of receipt of invalid HREC amendment application

Office of the Human Research Ethics Committee

[date]

[CPI Name]

[CPI Address]

Enquiries to:

Phone: [phone]

Fax: [Fax]

Our Ref: [HREC Reference]

E-mail [Email]

Dear [CPI Name]

HREC Reference number: [HREC Reference]

Project title: [Full Title]

Protocol number: [Where applicable]

Thank you for submitting the above amendment to the research project to the [HREC Name] Human Research Ethics Committee (HREC) for ethical and scientific review, which was received on [HREC Application Received Date].

Unfortunately, the application is not valid, for the following reasons:

[List reasons entered on Validation screen]

[Enter any other discrepancies].

You are welcome to re-submit the amendment application, taking into account the above points.

Detailed information about the Queensland Health process for submission and authorisation of research can be obtained from the Research Ethics and Governance Unit website:

http://www.health.qld.gov.au/ohmr/html/regu/regu_home.asp

Should you require any additional information, please contact the HREC Co-ordinator, [Co-ordinator Name] on [Phone] or [Email].

Yours sincerely

Co-ordinator

Human Research Ethics Committee

c.c. [name and address of research assistant if applicable]

SL22: Appointment Letter for HREC/SSC Member

Office of the Human Research Ethics Committee

[date]

Enquiries to:

Phone:

Fax:

Our Ref:

E-mail:

Address

QLD

Dear [name] ,

I am delighted to welcome you to the [HREC name] Human Research Ethics Committee, Queensland Health and thank you for accepting an appointment as a member of the Committee.

The position is a voluntary one and therefore unpaid. In accordance with the *National Statement on Ethical Conduct in Human Research 2007* and the *NHMRC and Universities Australia Australian Code for the Responsible Conduct of Research (2007)*, members are appointed for a period of up to three years after which it may be renewed, and 'are appointed for their knowledge, qualities and experience, and not as representatives of any organisation, group or decision'. This letter of appointment also formally acknowledges the indemnity provided by Queensland Health for your work as part of the Committee.

Meetings are held [insert number of meetings] times a year, generally on [Insert day of meeting] of the month at [Insert time and location of meeting]. I have attached the current meeting schedule, a National Statement and also a check-list about the type of information required in the applications submitted. The HREC office is located [insert address], and the office staff contact details are below. We ask that members review and monitor proposals as a lead or second reviewer and then discuss these and other submissions at the meeting. We also ask members to consider other submissions outside the committee structure in the case of expedited review of research or quality assurance projects which may be submitted for an ethical decision.

[Insert name and contact details of HREC Administrator and staff]

I look forward to welcoming you to meetings, and I hope you find the appointment enjoyable and rewarding.

Yours sincerely,

[name]

CHAIRPERSON

HUMAN RESEARCH ETHICS COMMITTEE

[name] HOSPITAL HEALTH SERVICE DISTRICT

SL24: Acknowledgement of Obligations/Acceptance of Appointment:

Agreement to Membership of the [name] Hospital Health Service District Human Research Ethics Committee

I _____ agree to serve on [name] Hospital Human Research Ethics Committee.

I understand that:

- The position is voluntary;
- The [name] Hospital Health Service District Human Research Ethics Committee (HREC) is constituted in accordance with the NHMRC “National Statement on Ethical Conduct in Research Involving Humans” (2007);
- In reviewing research proposals associated with Queensland Health, I will be indemnified by Queensland Health for any decisions or actions taken during the course of the Committee’s deliberations. Furthermore, for privately run commercially sponsored trials requesting review by a Queensland Health HREC, the private sponsor’s indemnity must name and indemnify the public hospital in providing ethical review of their research.
- The Committee’s business is confidential and I agree to maintain this confidentiality;
- I should be available to attend monthly meetings. If I am unavailable I should forward my reviews to the Human Research Ethics Committee Coordinator;
- I should inform the Chairperson if I require leave of absence or if I am unable to attend 3 or more consecutive meetings.
- I warrant that as at the date of this document, to the best of my knowledge, no conflict of interest exists or is reasonably foreseeable in relation to the performance of my obligations under this agreement

- I agree to declare to the Committee any interests I may have in relation to an application for ethical review or any other matter for consideration at a HREC meeting.
- I agree to allow the following personal contact details to be stored on the INFONETICA Australian Research Database (AU – RED), an online application system for managing research ethics applications that is maintained by QH HRECs.

Privacy Notice:

Confidential personal information that is stored in the AU – RED application in the United Kingdom is protected by British Privacy Legislation – the *Data Protection Act 1998* (UK). Confidential personal information that is stored by Queensland Health is protected by the Departments Information Standard 42A (Privacy).

Name Postal Address Courier Address Email

Telephone Mobile Fax

Alternate Contact:

Name Postal Address Courier Address Email

Telephone Mobile Fax

Signature

Date

Please fill in the details below for HREC files. The HREC Coordinator will only enter into AU-RED those contact details agreed to under the “Terms and Conditions of Appointment”.

HREC Member Contact Details

Name

Postal Address

Courier Address

Phone (H)

Phone (W and/or Mobile)

Fax

Email:

Alternate Contact Details

Name

Postal Address

Courier Address

Phone (H)

Phone (W and/or Mobile)

Fax

Email:

SL25: Acknowledgement of receipt of complaint

Office of the Human Research Ethics Committee

[date]

[Name]

[Address]

Enquiries to:

Phone: [phone]

Fax: [Fax]

Our Ref: [HREC Reference]

E-mail [Email]

Dear [Name]

HREC Reference number: [HREC Reference]

Project title: [Full Title]

Protocol number: [Where applicable]

Your complaint of [enter complaint type] in regards to the above study was received on [enter date].

The complaint will be reviewed at the meeting of the [HREC], [Chairperson], [Deputy Chairperson], [Sub Committee], [Other] to be held on [Meeting date].

Should you require any additional information, please contact the HREC Co-ordinator, [Co-ordinator Name] on [Phone] or [Email].

Yours sincerely

Co-ordinator

Human Research Ethics Committee

SL26: Acknowledgement of resolution of complaint

Office of the Human Research Ethics Committee

[date]

[Name]

[Address]

Enquiries to:

Phone: [phone]

Fax: [Fax]

Our Ref: [HREC Reference]

E-mail [Email]

Dear [Name]

HREC Reference number: [HREC Reference]

Project title: [Full Title]

Protocol number: [Where applicable]

The complaint of [enter complaint type] in regards to the above study was reviewed at the meeting of the [HREC], [Chairperson], [Deputy Chairperson], [Sub Committee], [Other] held on [Meeting date].

The decisions from this and subsequent meetings are [insert decisions in dot point form].

This matter is now regarded as closed.

Should you require any additional information, please contact the HREC Co-ordinator, [Co-ordinator Name] on [Phone] or [Email].

Yours sincerely

Co-ordinator

Human Research Ethics Committee

SL27: Acknowledgement of Adverse event report

Office of the Human Research Ethics Committee

[date]

[CPI Name]

[CPI Address]

Enquiries to:

Phone: [phone]

Fax: [Fax]

Our Ref: [HREC Reference]

E-mail [Email]

Dear [CPI Name]

HREC Reference number: [HREC Reference]

Project title: [Full Title]

Protocol number: [Where applicable]

Thank you for sending the adverse event report for the above study dated [Progress Report Document Date].

The report [will be / was] reviewed at the meeting of the [HREC], [Chairperson], [Deputy Chairperson], [Sub Committee], [Other] held on [Meeting date].

Yours sincerely

Co-ordinator

Human Research Ethics Committee

c.c. [name and address of research assistant if applicable]

SF1: HREC Submission Checklist for Researchers – New Protocol

A copy of this checklist should be included with every new research project application submitted to the reviewing HREC:

A) Mandatory components for all submissions to an HREC		YES	No. of copies required
1.	Cover letter, with brief description of project, signed by Coordinating Principal Investigator For commercially sponsored studies the name and address of the sponsor organisation/CRA for the HREC review invoice (must be Australian address) must be included in the cover letter		
2.	For low and negligible risk (LNR) research studies – Completed LNR application form accessed from: http://www.health.qld.gov.au/ohmr/html/regu/for_researcher.asp		
3.	For all other studies: Completed online NEAF with "Submission Code" accessed from online NEAF website: https://ethicsform.org/au/SignIn.aspx		
3.	Study protocol (The NEAF / LNR research application form is not the study protocol)		
4.	CV for researchers who have not submitted a CV within last 2 years		

B) Other items that may be required depending on the particular research project application being submitted		YES	NO	N/A	No. of copies required
5.	Data collection tool(s) e.g CRF				
6.	Master Participant Information Sheet and Consent Form (PICF)				
7.	CTN/CTX form(s)				
8.	Investigator's Brochure				
9.	Questionnaires/other instruments				
10.	Form of indemnity (Medicines Australia HREC Review Only form)				
11.	Advertising materials (including a copy of transcript for advertisement, e-mail, website, letter or telephone call)				
12.	Letter of invitation/Letter to GP, etc.				
13.	Participant diaries				
14.	Participant wallet card				
15.	Other correspondence, e.g. FDA reviews, correspondence from other HRECs, expert independent reviews, peer review etc.				
Research using gene technology					
16.	<u>Institutional Biosafety Committee (IBC) approval</u>				
17.	Advice from the NHMRC Cellular Therapies Advisory Committee (CTAC)				
18.	Licence for dealings with a Genetically Modified Organism (GMO)				
Research which is using radiological procedures that are performed specifically for research					
19.	Independent assessment report or verification by a Medical Physicist (or District Radiation Safety Officer) of the total effective dose and relevant organ doses for those radiological procedures that are performed specifically for the research protocol				

- All documents must be collated and contain version numbers, version dates and page numbers.
- All supporting documents should be uploaded with the NEAF under the "Documents Tab" on the Online Forms website: <https://ethicsform.org/au/SignIn.aspx>
- Information on HREC closing dates and meeting dates can be found on the REGU website: HREC & Research Governance Officer Contacts http://www.health.qld.gov.au/ohmr/html/regu/hrec_contacts.asp
- The closing time for submissions is 12 midday. Please note: There are no exceptions to the closing time without prior agreement by the HREC Administrator

SF2: AU – RED Research Ethics Agenda
[GENERATED BY AU-RED]

A meeting of the [Insert name of HREC] Human Research Ethics Committee will be held on [Insert Date and Time of Meeting] in [Insert Meeting location].

A G E N D A

* Papers are attached for items marked with an asterisk.

1. APOLOGIES FOR ABSENCE

[List apologies]

2. DECLARATIONS OF INTEREST

[List Declarations]

3. MINUTES OF MEETING HELD ON [Insert previous meeting in database].*

4. MATTERS ARISING

[List Matters Arising]

5. NEW APPLICATIONS FOR ETHICAL REVIEW *

[List new applications]

6. AMENDMENTS FOR ETHICAL REVIEW *

[List New amendments]

7. SERIOUS ADVERSE EVENTS *

[List new SAE's]

8. OTHER BUSINESS

[List other Business]

9. OTHER BUSINESS FOR INFORMATION

[List Other Business]

10. GENERAL BUSINESS

[List General Business]

11. DATE OF NEXT MEETING

The next meeting of the [Insert Name] HREC will be held on TBD.

SF3: HREC Cover Sheet for New Protocols

PROPOSED RESEARCH PROTOCOL FOR CONSIDERATION

BY THE

SCIENTIFIC SUB-COMMITTEE

AND/OR THE

HUMAN RESEARCH ETHICS COMMITTEE

PROTOCOL[prot no] : [protocol title]

PRINCIPAL INVESTIGATOR: [PI's name and address]

SPONSOR: [sponsor's name, if any]

HREC Ref. No.

Date Received by Coordinator

[closing date]

Date for Review by Scientific Sub-Committee

[ssc meeting date]

Date for Review by Human Research Ethics Committee
[hrec meeting date]

SF4: Agreement for the Conduct of Expert Review (Volunteer Panel)

Agreement to provide Expert Review for a Queensland Health Human Research Ethics Committee (QH HREC)

The State of Queensland acting through Queensland Health “QH”

[Name of Independent Reviewer] of [address] “You”

Background

QH appoints you to a panel of volunteers who conduct independent expert reviews of various research applications, the details of which will be provided to You by a QH HREC (“the Review”). You agree to conduct each Review in accordance with the terms of this document.

Conduct of Review

1. The review is conducted in a diligent and professional manner. You warrant that you have the qualifications, skills and expertise to conduct each Review.
2. Each Review will consist:
 - A written report to QH that addresses those issues identified as ‘Review Issues’ by the QH HREC.
 - The report clearly identifies those issues on which you have not or cannot form an opinion, and if possible, the reasons for this.
 - If you have made assumptions in forming your opinion, you should identify them.
 - If you have relied on the opinion of some other person in forming your opinion, you should identify that other opinion.
 - If requested you must rewrite any part of your report that is considered by QH as being ambiguous or unclear or requiring further development.
 - Promptly clarify any queries raised by the reviewing QH HREC in relation to the Review Issues.
 - The reviewing HREC may ask you to attend, or teleconference into a meeting of the relevant HREC at which your written report concerning the Review is considered.
 - You conduct each Review in accordance with the National Health and Medical Research Council’s (NHMRC) *National Statement on Ethical Conduct in Human Research (2007)* and any relevant laws and guidelines.

Permission to Disclose Personal Details

4. Your personal contact details may be communicated to the members of the relevant HREC.
5. Your details will be entered into the INFONETICA Australian – Research Ethics Database (AU-RED) maintained by QH.

Privacy Notice:

Confidential personal information that is stored in the AU-RED application in the United Kingdom is protected by British privacy legislation – the Data Protection Act 1998 (UK). Confidential personal information that is stored by QH is dealt with in accordance with the Information Privacy Act 2009.

Privacy

6. *In relation to any personal information You collect or have access to for the purposes of performing a Review, You agree to comply with parts 2 and 3 of Chapter 2 of the Information Privacy Act 2009 as if You were QH.*

Intellectual Property Rights

7. All intellectual property rights arising out of the performance of each Review will immediately vest in QH.

Confidentiality

8. You must not use, copy, disclose, reproduce or make public QH's Confidential Information for any purpose except in accordance with this document. You may use QH's Confidential Information for the purpose of conducting the review/s. If You become aware of a breach of this obligation, You must immediately notify QH.
10. You must not disclose any of QH's Confidential Information unless one of the following circumstances applies:
 - (a) QH has consented in writing to the disclosure.
 - (b) The disclosure is required by law.
11. If requested by QH, upon conclusion of each Review, You must return to QH all papers, records and documents in Your possession which relate in any way to the relevant research application that were provided by QH or contain QH's Confidential Information.
12. Your obligations of confidence set out in this document continue in full force and effect after this document ends.
13. In this document Confidential Information means any information provided by QH or any of its employees, officers, agents or contractors to You, or otherwise obtained by You, whether obtained before or after execution of this document, in connection with QH, a Review or this document. It includes:
 - (a) all confidential business or clinical information, documents, records, financial information, reports, technical information and forecasts which relate to QH or QH's business, staff or patients;
 - (b) QH's intellectual property;
 - (c) the terms and conditions of this document; and
 - (d) any information created under or arising out of the conduct of a Review under this document.

It does not include:

- (e) information which is in or becomes part of the public domain, other than through a breach of this document or an obligation of confidence owed to QH; or
- (f) which You can prove by contemporaneous written documentation was independently acquired or developed without breaching any of the obligations set out in this document.

Conflict of Interest

14. You must not undertake any work or perform any services for other parties which may conflict with Your obligations as an independent expert reviewer. You warrant that as at the date of this document to the best of your knowledge no conflict of interest exists or is reasonably foreseeable in relation to the performance of Your obligations under this document.

Indemnity

- 15. As a volunteer performing duties or functions on behalf of QH, You will be indemnified by QH in accordance with the provisions of HR Policy I3.

Term and termination

- 16. This agreement takes effect on the date of this document and remains in force for a period of 5 years, unless terminated in accordance with this document.
- 17. Either party may terminate this document by giving 30 days written notice to the other party.

Execution

Signed for and on behalf of QH in the presence of:

.....
Signature of witness

.....
Signature of authorised person

.....
Name of witness (print)

.....
Name of authorised person (print)

...../...../.....
Date

Signed by [Name of Expert Reviewer] in the presence of:

.....
Signature of witness

.....
Signature of Expert Reviewer

.....
Name of witness (print)

SF5: Queensland Health External Expert Research Proposal Review Report Form

ASSESSMENT OF VALIDITY & QUALITY OF RESEARCH PROTOCOLS
RESEARCH REVIEW FORM: COVER SHEET

Research Protocol for Review by External Expert Reviewer:

PROTOCOL NO.

PROTOCOL TITLE:

PROTOCOL VERSION:

HREC REF. No.

Expert External Review Requested by:

[HREC Administrator's name]

The HREC Administrator,
c/o HREC,
Health Service District
[Postal Address]

Date Sent by HREC Administrator:/...../.....
[Date]

Requested Date for Return:/...../.....
[Date]

External Expert Review Requested from:

Name:
Contact Details:

For Completion by the External Expert Reviewer

Date Received:/...../.....
[Date]

Date Sent to HREC:/...../.....
[Date]

I,

- agree
- do not agree

to undertake the review and assessment of the validity and quality of the attached research protocol whilst abiding by the obligations of my appointment as a Expert Reviewer of the QH [Institution Name] Hospital HREC.

...../...../.....
[Signature of External Expert Reviewer] [Date]

ASSESSMENT OF VALIDITY & QUALITY OF RESEARCH PROTOCOLS

SUGGESTED RESEARCH REVIEW QUESTIONS

PROTOCOL NO.....

PROTOCOL TITLE:.....

PROTOCOL VERSION:.....

HREC REF. No.....

Please refer to The NHMRC's *National Statement on Ethical Conduct in Human Research (2007)*.

Below are a range of suggested questions to address in providing a scientific review of this proposal. Please feel free to comment or address additional issues as you see fit.

General Questions to Consider:

(Please provide explanations for answers)

- Does this research proposal demonstrate that the research is justifiable in terms of its potential contribution to knowledge?
- Is the research based on a thorough study of current literature as well as prior observation, approved previous studies, and where relevant, laboratory and animal studies?
- Is the research proposal designed to ensure that any risks of inconvenience, discomfort or harm to participants are balanced by the likely benefit/s to be gained?
- What is the overarching design of this research? Eg. qualitative, quantitative, observational and experimental?
- Is the proposal complete or is further information or evidence required to support their aims, hypothesis or proposed experimental methodology?
- Are there any design or other deficiencies within the proposal that require modification?
- Are there points of uncertainty or ambiguity that require clarification?

Specific Questions / Points to Consider Concerning the validity and quality of the research protocol

The Project

- Is the hypothesis / aim clear and valid?
- Does the literature / evidence support this?
- Is the research question useful? Is the research worthwhile?
- Is the research likely to yield new information, enhance understanding or clarify existing uncertainty?
- Has this, or similar research been carried out before or in the same or similar contexts?
- Can the research Proposal be supported by systematic review of the literature that would demonstrate the importance of the research questions and that it builds on the results of previous research?
- If indicated, have the perspectives of potential participant groups, the wider community, or other disciplines been incorporated into the research proposal?
- Does the value of the project appear to be adequate to justify its conduct with humans? (or animals if relevant?)
- Is the rationale sound? What are the clinical implications (if any) of the expected results for this study?

The Researchers

- Do the researchers have necessary qualifications, competence and experience?

The Methodology and Research Design

- Are all aspects of research methodology clearly described?
- Is the methodology appropriate to achieve the aims/intent of the project?
- Review methodology, for example appropriateness of design in terms of:
 - randomisation/stratification,
 - sample size,
 - objectives,
 - design issues (e.g. placebo controlled, blinding, crossover, washout),
 - outcomes,
 - inclusion/exclusion criteria
 - Analysis and statistical validity
- Has the protocol adequately addressed research specific safety issues?
- How valid / effective are the participant information sheets (if any) and other documents in relation to the protocol?

SF9: HREC Minutes [generated by AU-RED]

Minutes of the meeting of the [Insert Name of District/Site] held on [Insert date] at [Insert time] in [Insert location of meeting]

Present:

Name	Profession	Capacity

Written comments received from:

Name	Position

1. APOLOGIES FOR ABSENCE

Apologies for absence were received from:

2. DECLARATIONS OF INTEREST

3. MINUTES OF MEETING HELD ON [Insert date of previous meeting]

The minutes of the previous meeting were agreed and signed by the Chairperson as a true record.

4. MATTERS ARISING

[List Descriptions]

5. NEW APPLICATIONS FOR ETHICAL REVIEW

5.1 08/AUT1/3 ATTOM Trial

Co-ordinating Principal
Investigator:
Type of review:
Sponsor:
Lead reviewer:
Second reviewer:

The Committee reviewed the above study.

In discussion, the Committee noted the following ethical issues.

[Summarise the main ethical issues discussed. List any important further information provided by the applicant, or issues clarified in discussion with the Committee. If giving a not approved decision, explain the reasons in full.]

Decision

[Describe decision]

6. AMENDMENTS FOR ETHICAL REVIEW

7. SERIOUS ADVERSE EVENTS

8. OTHER BUSINESS

8.1 Arrange new meeting date

Description: Agreed 14th April 2008

11. OTHER BUSINESS FOR INFORMATION

12. GENERAL BUSINESS

13. DATE OF NEXT MEETING

The next meeting of the HREC will be held on 20 March 2008 at 08.00 in Meeting Room 3, 3rd Floor, Queensland Health Building.

.....
Signed – Chairperson

.....
Date

.....
Signed – HREC Co-ordinator

.....
Date

Copy to: All committee members
Co-opted/Co-opted members who attended the meeting

SF10b: Composition of HREC to reporting to institution



**Queensland Health Central Office
Human Research Ethics Committee**

EC0034

The following is the current composition of the Queensland Health Central Office Human Research Ethics Committee.

It is advised that the Committee abides by the guidelines of the National Health and Medical Research Council's *National Statement on Ethical Conduct in Human Research (2007)*.

It is also advised that the investigator(s) for a study are not involved in the deliberations regarding HREC approval of a study.

Attendance at a Committee meeting is in accordance with Guidance of the National Statement Section 5.2.30.

Name	COMPOSITION OF HREC as per National Statement 5.1.30	MALE OR FEMALE	HOSPITAL AFFILIATION (Y/N)
	Chair		
	Deputy Chair - Expert in research areas		
	Religious representative		
	Expert in research areas		
	Expert in research areas		
	Expert in research areas		
	Lawyer		
	Layperson		
	Layperson		
	Expert in professional care		
Non voting HREC advisors			
	HREC Advisor (non voting)		
	HREC Administrator (non voting)		

Should you require any additional information, please do not hesitate to contact the Queensland Health Research Ethics and Governance Unit: 07 323 40034 or REGU@health.qld.gov.au.

SF11: Research Commencement Form

**HUMAN RESEARCH ETHICS COMMITTEE
NOTIFICATION OF COMMENCEMENT OF
RESEARCH PROTOCOL**

PROTOCOL NO: _____

PROTOCOL TITLE: _____

PRINCIPAL INVESTIGATOR: _____

This is to advise that the above research protocol commenced on:

_____/_____/_____

Signature: _____ **Date:** ____/____/____

Please forward to HREC when protocol commences

SF12. NHMRC Requirements

Office of the Human Research Ethics Committee/District Executive Office

[date]

Enquiries to:

Phone:

Fax:

Our Ref: [prot no]

E-mail:

[FULL NAME AND ADDRESS]

Dear [NAME]

[protocol no, full title, sponsor protocol number if applicable]

Listed below are practices specified by the National Health and Medical Research Council to which research workers must adhere for responsible research conduct.

1. Research Data and Records Management:

- (i) Data, including electronic data, must be recorded in a durable, appropriately indexed and retrievable form.
- (ii) Sound research procedures entail the discussion of data and research methods with colleagues. Discussion may also occur well after the research is complete, often because of interest following publication. If at all possible, it is in the interests of all research workers to ensure that original data are safely held for a minimum of 5 years from the date of publication. For specific types of research (eg. Clinical trials), 15 years or more may be appropriate.
- (iii) Wherever possible, original data should be retained in the department or research unit in which they were generated. In some cases, such as when data is obtained from limited-access data bases, or in a contracted project, it may not be possible to hold them in this way.

In such cases, a written indication of the location of the original data, or key information regarding the limited-access data base from which it was extracted, must be kept in the department or research unit. Individual researchers should be able to hold copies of the data for their own use.

- (iv) Ensure that when research data is not in direct use, the information and records are kept in safe and secure storage and in a manner that protects the privacy of participants, and are in accordance with any confidentiality agreements that may apply.

2. Publication and Authorship of Research findings

- (i) Researchers must register clinical trials with a recognised, publicly accessible, clinical trials register prior to implementation of the research to promote access to all clinical trial results.
 - a. The criteria for authorship of a publication must be determined and announced by each research unit or department. Each co-author must acknowledge his/her co-authorship in these terms, in writing, and that this must be kept on file in the department or unit of the responsible or executive author. If, for any reason, one or more co-authors are unavailable or otherwise unable to sign the statement of authorship, the head of the research unit or department may sign on their behalf, noting the reason for their unavailability.
 - b. Where there is more than one author of a publication, one author (by agreement among the authors) should formally accept overall responsibility for the entire publication. Such formal acceptance must be in writing, and kept on file in the department or unit of that author, together with the names and signatures of all other authors.

- c. In general an individual **should meet all of the three following conditions** to be included in the authorship manuscript list:
- (ii) Substantial contributions to conception and design, or acquisition of data, or analysis and interpretation of data;
 - (iii) Drafting the article or revising it critically for important intellectual content and;
 - (iv) Final approval of the version to be published.
- d. A person who does not fulfil the above criteria should not be included as an author of a publication. Acquisition of funding, acquisition of data, or general supervision of the research group, alone, does not justify authorship.
- (vi) Due recognition of all participants is a part of a proper research process. Authors should ensure that the work of non-authors, including research assistants and technical officers is properly acknowledged. Where individuals are named, their consent must first be obtained.
 - (v) Publication of multiple papers based on the same set(s) or subset(s) of data is improper unless full cross-referencing occurs within the papers (for example, by reference to a preliminary publication at the time of publication of the complete work, which grew from it). Simultaneous submission of papers based on the same set(s) or subset(s) of data to more than one journal or publisher should be disclosed to each journal or publisher at the time of submission.
 - (vi) Researchers must acknowledge the host institution and funding sources of the research. A manuscript should include a statement that the research has not been subject to result-dependent funding or veto of publication by a sponsor and/or government.
 - (vii) Institutions must ensure that the sponsors of research understand the importance of publication in research and do not delay publication beyond the time needed to protect intellectual property and other relevant interests. Government sponsors should have a right to review the manuscript for a defined period of time before publication to allow strategies and/or policies to be developed in response to the research findings. The maximum delay in publication should be stated in the protocol and CTA.
 - (viii) Research projects should not be approved by an HREC retrospectively.

3. Student/Research Trainee Supervision

- (i) Supervision of each research student/trainee investigator (including honours, masters, doctoral and junior postdoctoral research workers) should be assigned to a specific, responsible and appropriately qualified senior research worker in each research unit or department.
- (ii) The ratio of students/trainee to supervisors should be small enough to assure effective scientific interaction, as well as effective supervision of the research at all stages.
- (iii) Research Supervisors should oversee all stages of the research process and advise each trainee of applicable government and institutional guidelines for the conduct of research, including those covering ethical requirements for studies on human or animal participants, and requirements for students involving potentially hazardous agents.
- (iv) Research supervisors should be primary sources of guidance to research students/trainees in the matters of sound scientific practice.
- (v) As far as possible, research supervisors should ensure that the work submitted by research students/trainees is their own and that, where there are data, they are valid.

4. Disclosure of potential conflict of interest

Research workers must disclose to the Human Research Ethics Committee affiliation with or financial involvement in, any organisation or entity with a direct interest in the subject matter or materials of research workers including benefits in kind such as the provision of benefits (e.g. travel and accommodation expenses to attend conferences). Such disclosures will be held in

confidence by the Human Research Ethics Committee although the NHMRC requires disclosure of all affiliations with or financial involvement in any organisation or entity with a direct commercial interest in any research it supports.

SF13: Checklist and application for Exempt and Low Risk Research

Advice regarding negligible and low risk ethical review processes.

The National Health and Medical Research Council (NHMRC) “National Statement on Ethical Conduct in Human Research 2007, herein called “The National Statement”, http://www.nhmrc.gov.au/publications/ethics/2007_humans/contents.htm recognises that human research involves a wide range of activities that have variable risks and potential benefits. The “National Statement” establishes different levels of ethical review, based on the degree of risk involved.

There are three levels of risk:

- Harm;
- Discomfort;
- Inconvenience

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.

Negligible Risk Research

The National Statement Section 2.1.7 describes research as “negligible risk” where there is no foreseeable risk of harm or discomfort; and any foreseeable risk is not more than inconvenience to the participants. Where the risk, even if unlikely, is more than inconvenience, the research is not negligible risk. The National Statement describes inconvenience as the least form of harm that is possible for human participants in research. The most common examples of inconvenience in human research are filling in a form, participating in a de-identified survey or giving up time to participate in a research activity.

Institutions may choose to exempt from ethical review research that:

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

Low Risk Research

The National Statement Section 2.1.6 describes research as “Low Risk” where the only foreseeable risk is one of discomfort. Discomforts may include minor side-effects of medication, discomforts related to measuring blood pressure or anxiety induced by an interview. Where the risk, even if unlikely, is more serious than discomfort, the research is not low risk. However, for research involving certain groups, methodologies or procedures only full HREC review is allowable, irrespective of the level of the risk (see checklist)

Institutions may establish non-HREC levels of ethical review for low risk. The levels of ethical review may include, but need not be limited to:

- e. review or assessment at departmental level by the head of department;
- f. review or assessment by a departmental committee of peers (with or without external or independent members);
- g. delegated review with reporting to an HREC; or
- h. review by a subcommittee of an HREC.

It is the institute’s responsibility to determine which level of ethical review process is implemented for low and negligible risk research. Researchers should consult with their local HREC office / RGO for advice on where to submit their low and negligible risk research application.

For all low and negligible risk research studies, the “Checklist for Research that is Exempt from full HREC review” and “Application for Ethical Review of Negligible or Low Risk Research” must be completed and submitted to the institution’s low and negligible risk review panel.

Research Greater than Low Risk

Research involving more than low risk must be reviewed and approved by a fully constituted HREC. A full HREC application must be prepared using the online Queensland Health NEAF accessed at <http://www.ethicsform.org/au/SignIn.aspx>.

Collection, Storage and Disclosure of Data

The National Statement Section 3.2 identifies data may be collected, stored or disclosed in three mutually exclusive forms:

- ***individually identifiable data***, where the identity of a specific individual can reasonably be ascertained. E.g the individual’s name, image, date of birth or address;
- ***re-identifiable data***, from which identifiers have been removed and replaced by a code, but it remains possible to re-identify a specific individual by, e.g, using the code or linking different data sets;
- ***non-identifiable 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.
- ***de-identified data***, the National Statement avoids the term, as its meaning is unclear. While it is sometimes used to refer to a record that cannot be linked to an individual (‘non-identifiable’), it is also used to refer to a record in which identifying information has been removed but the means still exist to re-identify the individual. When the term ‘de-identified data’ is used, researchers and those reviewing research need to establish precisely which of these possible meanings is intended.

Checklist for Research that is Exempt from full HREC review

Researchers are encouraged to complete the checklist first and consult with the local HREC office / RGO to gain an independent assessment of whether the project satisfies the criteria for alternative review to that by a full HREC. Time constraint is not an acceptable reason for seeking review through this process where projects carry risks greater than discomfort.

Projects that are not deemed eligible for exemption from full HREC review are forwarded to the HREC for consideration and approval in the usual way. A full HREC application must be prepared using the online Queensland Health NEAF accessed at <http://www.ethicsform.org/au/SignIn.aspx>.

NHMRC "National Statement on Ethical Conduct in Human Research"

Sections 2.1.7, 5.1.18 – 5.1.23

If the project includes any of the nine following types of research and/or participants it will require full review by a HREC and will **not be eligible for low risk review**.

- Interventions and therapies, including clinical and non-clinical trials and innovations of new treatment modalities
- Human genetics
- Human stem cells
- Women who are pregnant and the human foetus;
- People who are highly dependent on medical care who may be unable to give consent;

- People with a cognitive impairment;
- People with an intellectual disability or a mental illness;
- Research specifically targeting Aboriginal or Torres Strait Islanders;
- People who may be involved in illegal activities

- For Quality Assurance activities (including, types of audits or quality assurance) as guided by the QH Clinical Governance Implementation Standard *Clinical Audit & Review* http://www.health.qld.gov.au/cpic/documents/clinaudrevstand_v1.pdf submit to a local QA Committee or consult with your local HREC office / RGO for advice.

- For further information on Quality Assurance Committees please refer to the Clinical Practice Improvement Centre website: http://www.health.qld.gov.au/cpic/quality_strategy/quality_assur_com.asp.

If a project does **NOT** include any of the above, complete the detailed checklist below to ascertain whether the proposed research is eligible for consideration for low risk review by the institution's low risk review process. A 'yes' answer to any of the below does not necessarily automatically preclude the research from being reviewed through a low risk review process

1. Are any of the following topics covered in part or in whole?

- | | | |
|--|------------------------------|-----------------------------|
| ▪ Research about parenting issues | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| ▪ Research investigating sensitive personal issues | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| ▪ Research investigating sensitive cultural issues | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| ▪ Explorations of grief, death or serious/traumatic loss | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| ▪ Mental Disorders eg Depression, mood states, anxiety | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| ▪ Gambling | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| ▪ Eating disorders | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| ▪ Illicit drug use | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| ▪ Substance abuse (prescribed or over the counter) | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| ▪ Self report of criminal behaviour | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| ▪ Any psychological disorder | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| ▪ Suicide risks | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| ▪ Gender identity | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| ▪ Sexuality | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| ▪ Race or ethnic identity | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| ▪ Any disease or health problem | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| ▪ Fertility | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| ▪ Termination of pregnancy | Yes <input type="checkbox"/> | No <input type="checkbox"/> |

2. Are any of the following procedures to be employed?

- | | | |
|---|------------------------------|-----------------------------|
| ▪ Use of personal data obtained from Commonwealth or State Government Department/Agency with participant consent | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| ▪ Deception of participants | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| ▪ Concealing the purposes of the research | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| ▪ Covert observation (or minimal disclosure) | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| ▪ Audio or visual recording without consent | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| ▪ Recruitment of a third party or agency | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| ▪ Withholding from one group specific treatments or methods of learning, from which they may "benefit" (e.g. in medicine or teaching) | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| ▪ Psychological interventions or treatments | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| ▪ Involvement of any experimental manipulation or includes the presentation of any stimulus other than question-asking; | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| ▪ Invasive physical procedures | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| ▪ Infliction of pain | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| ▪ Administration of drugs | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| ▪ Administration of other substances or devices | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| ▪ Exposure to ionising radiation | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| ▪ Tissue sampling or blood for pathological or genetic testing | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| ▪ Collecting body fluid (eg. saliva) | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| ▪ Use of medical records where participants can be identified or linked | Yes <input type="checkbox"/> | No <input type="checkbox"/> |

3. Other Risks

- Are there any potential risks to the researcher? (e.g. research conducted in unsafe environments or trouble spots)? Yes No
- Are there any potential risks to non participants in the research, such as, participant's family members and social community? e.g. effects of biography on family and friends or infectious disease risk to the community) Yes No

4. Select the categories that are targeted or likely to be included as participants in this research project.

- Suffers from a psychiatric / psychological disorder / emotional impairment Yes No
- Suffering a physical disability or medical condition Yes No
- Participants are aged less than 18 years; Yes No
- Children and/or young people without parental or guardian consent Yes No
- Resident of a custodial institution Yes No
- Unable to give freely an informed consent because of difficulties in understanding information provided (eg. Language difficulties, NESB) Yes No
- Members of a socially identifiable group with special cultural or religious beliefs or political vulnerabilities Yes No
- Participants specifically targeted belong to a cultural/minority group or any other collectivity Yes No
- Those in a dependent relationship with the researchers (eg. Lecturer/student, doctor/patient, teacher/pupil & professional/client) Yes No
- Participants are identifiable or re-identifiable Yes No
- Participants are identifiable in the final report when specific consent for release has not been given Yes No
- Research findings are expected to be published in a peer reviewed Journal Yes No

If "No" has been answered to all the above questions, the project is eligible for review under the alternative method for low risk review established by the institution.

A 'yes' answer to any item in the checklist 1 – 4 indicates that the project would normally **not be eligible** for low risk review. However, a 'yes' answer does not necessarily, automatically, preclude the research from being reviewed through a low risk review process. A project may still be deemed low risk if the following considerations are reasonably justified with the provision of detailed information to the following:

- The likelihood and severity of the risks (any risk greater than discomfort, even if unlikely, is not low risk);

- Indication of those participants and/or others the risk may affect:

- Indication of ways to minimise the risk;

- The potential benefits of the research;

- Indication of those that the benefits are likely to accrue.

If any item in the checklist 1 – 4 has been answered 'yes' it is advisable to consult with your HREC office/RGO, to gain an independent assessment of whether the project satisfies the criteria for alternative review to that by a full HREC, **prior to** completing the 'Application for Ethical Review of Negligible or Low Risk Research'

Application for Ethical Review of Negligible or Low Risk Research

About this Form:

This application form should be used by researchers seeking ethical approval for human research projects that have been assessed by the Queensland Health "**Checklist for Research that is Exempt from full HREC review**" as presenting no more than low risk to research participants. **The completed checklist must be attached to this form.**

Completing the Form:

The Queensland electronic Low Risk Research Application Form may be accessed on <http://www.ethicsform.org/au> (available late 2009) or accessed from the Research Ethics and Governance Unit website: http://www.health.qld.gov.au/ohmr/html/regu/for_researcher.asp.

Signatures can be applied in the required spaces once the completed form is printed.

Attachments:

If completing the form electronically (available late 2009), before submitting your application, please check that you have electronically attached the completed "Checklist for Exempt and Low Risk Research" and copies of all required supplementary documentation (eg: Participant Information Sheet and Consent Forms).

Authorisations:

Please check that you have obtained all required signatures before submitting the application.

Submitting the Application:

Submit the completed and signed original application, the "**Checklist for Research that is Exempt from full HREC review**", and any attachments to the designated review personnel at your Institution / Health Service District.

Do not commence research until written approval has been received from the District CEO or delegate.

Application for Ethical Review of Negligible or Low Risk Research

SECTION 1: RESEARCHERS (Include all researchers)

1.1 Coordinating Principal Investigator / chief researcher

Title	
Surname	
Forename	
Mailing Address	
Suburb /City	
Postcode	
Country	
Organisation name	
Department	
Email	
Phone (BH)	
Mobile	

** For single centred studies the principal investigator and the Coordinating Principal Investigator will be the same person.*

1.2 Principal Investigator(s)

Title	
Surname	
Forename	
Mailing Address	
Suburb /City	
Postcode	
Country	
Organisation name	
Department	
Email	
Phone (BH)	
Mobile	

1.3 Associate Investigator(s)

Title	
Surname	
Forename	
Mailing Address	
Suburb /City	
Postcode	
Country	
Organisation name	
Department	
Email	
Phone (BH)	
Mobile	

1.4 Contact person for the project

Title	
Surname	
Forename	
Mailing Address	
Suburb /City	
Postcode	
Country	
Organisation name	
Department	
Email	
Phone (BH)	
Mobile	

1.5 Researcher/s Qualification, Experience and Skills:

List academic qualifications and outline experience and skills relevant to project that researcher/s and any supporting staff have in undertaking the research. (100 words max)

--

SECTION 2: Project Details:

(NHMRC "National Statement on Ethical Conduct in Human Research 2007", section 1)

2.1 Project Title:

--

2.2 Project plan:

Multi centred site research

Single centred site research

2.3 Broad area of research

2.3.1 Please select the broad area of research (one only)

Basic Science	<input type="checkbox"/>
Clinical Medicine & Science	<input type="checkbox"/>
Preventative Medicine	<input type="checkbox"/>
Health Services Research	<input type="checkbox"/>
Public Health	<input type="checkbox"/>

2.4 Lay Description:

Briefly outline in simple terms the project's aim(s), justification, participant group(s), method and possible outcomes. (150 words max.)

2.5 Research Methodology:

Outline the proposed method, including data collection techniques, tasks participants will be asked to complete; estimated time commitment required of them; and how data will be analysed. Give a justification of your proposed sample size, including details of statistical power of the sample where appropriate. (600 words max)

Type of research

Research design

Methods used to achieve aims

Statistical methodology (including sample size):

Data collection techniques

Participant tasks and time involved

Data analysis

Other comments

2.6 Research Aims and Significance:

State the aims, research objectives, key research questions, and significance of the project. Where relevant, state the specific hypothesis to be tested. Also please provide a brief description of the relevance of your proposed project to current research, a justification as to why your research should proceed and an explanation of any expected benefits to the community. Comment on its potential to contribute to existing knowledge, treatment, disease prevention, health promotion or social improvement. (600 words max.)

Key Research question(s):

Aims / Objectives:

Hypothesis:

Significance of project:

Relevance to current research:

Justification:

Expected benefits to the community:

Potential contribution to knowledge, treatment, disease prevention, health promotion or social improvement:

Other comments:

2.7 Provide the anticipated start and finish dates for the research project

2.7.1 Start date * / /

2.7.2 Finish date # / /

2.7.3 Duration (months):

* Start date refers to the first point of recruitment i.e. the date when the advertising or screening for participants begins.

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

SECTION 3: Other Approvals

(NHMRC "National Statement on Ethical Conduct in Human Research", Chapter 5.3)

The Principal Researcher is responsible for informing each ethical review body of all other Australian sites at which the research is being proposed or conducted, at the time of submission of the research project; of any previous decisions regarding the research made by another ethical review body; and informing each ethical review body of whether the protocol is presently before another ethical review body.

3.1 Is this protocol being submitted or has it been previously submitted to another ethical review bodies? Yes

No

If yes, provide details of other centres involved; the approval status of the study at each centre; and details of any required amendments.

Other External Approvals/Reviews?

If your research has undergone peer review, review from a funding body or involves participants from other organisations, copies of letters of approval or reviews must be attached to this application (if pending at the time the application is submitted, forward to HREC/low risk review Committee when available). In some cases, institutions/authorities may decline to provide approval letters until ethics approval has been granted. In such cases, you should submit your application to the HREC for provisional approval pending receipt of the documentation.

3.2 Has the research undergone peer review, review from a funding body or does it involve participants from other organisations?

Yes

No

If yes, please specify from whom and attach a copy of the communication:

SECTION 4: Recruitment of Participants

(NHMRC "National Statement on Ethical Conduct in Human Research 2007", Chapter 2.2)

4.1 Participant Details:

Provide number, age range and source of participants. This explanation should also include how potential participants will be identified and how initial contact will be made.

4.2 What is the proposed method of recruitment of participants?

SECTION 5: Consent

(NHMRC "National Statement on Ethical Conduct in Human Research 2007", Chapter 2.2, 2.3)

Informing Participants: Participant Information Sheet and Consent Form

The potential participant must be provided with information **at their level of comprehension** about the purpose, methods, demands, risks, inconveniences, discomforts, and possible outcomes of the research (including the likelihood and form of publication of research results).

5.1 Will the research involve informed consent of participants?

Yes

No

If yes, how will informed consent be obtained/recorded?

If no, please justify why consent will not be obtained?

SECTION 6: Information Protection (Confidentiality, Data Storage and Security)
(NHMRC "National Statement on Ethical Conduct in Human Research 2007", section 1 and NHMRC, Universities Australia "Australian Code for the Responsible Conduct of Research 2007", Section 2)

6.1 Confidentiality:

Explain what methods will be used to guarantee confidentiality/anonymity of participant data.

6.2 Data Storage and Security:

Explain how and where data will be held, including any arrangements for data security during?

6.3 Please indicate how long the data will be kept?

6.4 How will data be disposed of?

SECTION 7: Dissemination of Results

(NHMRC "National Statement on Ethical Conduct in Human Research 2007", section 1 and NHMRC, Universities Australia "Australian Code for the Responsible Conduct of Research 2007", Section 4)

7.1 Explain when, how, where and to whom results will be disseminated, including whether participants will be provided with information on the findings or outcomes of the project.



SECTION 8: Declarations

Signatures and undertakings:

Applicant/Principal Researchers (including Students and Supervisors where permitted)

I/we certify that:

- All information is correct and complete as possible;
- I/we have had access to and read the NHMRC "*National Statement on Ethical Conduct in Human Research*" (2007)
 - The research will be conducted in accordance with the National Statement;
- I/we have consulted any relevant legislation and regulations, and the research will be conducted in accordance with these;
- I/we will immediately report to the low risk ethical review body anything which might warrant review of the research, including:
 - Serious or unexpected adverse effects on participants;
 - Complaints;
 - Proposed changes in the protocol; and
 - Unforeseen events that might affect continued ethical acceptability of the project;
- I/we have attempted to identify all the risks related to the research that may arise in conducting this research and acknowledge my obligations and the rights of participants;
- I/we will not continue the research if ethical approval or site authorisation is withdrawn and will comply with any special conditions required by the low risk ethical review body, including:
 - Conditions of approval stipulated by the low risk ethical review body;
 - Cooperate with monitoring requirements. At a minimum annual progress reports and a final report will be provided to the low risk ethical review body.
- I/we have the appropriate qualifications, training, experience and facilities to conduct the research set out in the attached application and to deal with any emergencies and contingencies related to the research that may arise;
- This project complies with the Queensland Health guidelines for submission for Low Risk Research review.

Researcher name	Designation	Signature	Date

Designation means designated title related to the project eg Coordinating Principal Investigator, principal investigator, co investigator, student, study coordinator, site sponsor if principal researcher not a Qld Health employee etc

SECTION 9. Low and Negligible Risk Research Site-Specific Assessment

SSA is a component of research governance. It involves assessing the suitability of a site at which the research is being conducted and identifying whether the 'actual' and or 'in kind' resources required for the conduct and completion of the project can be met by the District. The SSA is the mechanism for financial accountability and transparency and is consistent with the Queensland Government *Financial Management Standard (1997)*. It is also a means by which Districts may quantify the contribution made by Queensland Health and manage and plan budgets.

You may be required to duplicate some of the details from Sections 1 – 8. This is because in some institutions Sections 1-8 may be processed by a different department to the department reviewing Section 9 and therefore all details are required to be completed.

9.1 Research details

Title (in full):

Short title (if applicable):

Name the sites applicable to this SSA Form, where the research will be conducted:

9.2 Researcher(s)

Please provide a list of the researchers' names at this site

9.2.1 Coordinating Principal Investigator / chief researcher for this site

Title	
Surname	
Forename	
Mailing Address	
Suburb /City	
Postcode	
Country	
Organisation name	
Department	
Email	
Phone (BH)	
Mobile	

9.2.2 Principal Investigator(s) for this site

Title	
Surname	
Forename	
Mailing Address	
Suburb /City	
Postcode	

Country	
Organisation name	
Department	
Email	
Phone (BH)	
Mobile	

9.2.3 Associate Investigator(s) for this site

Title	
Surname	
Forename	
Mailing Address	
Suburb /City	
Postcode	
Country	
Organisation name	
Department	
Email	
Phone (BH)	
Mobile	

9.3. Contact person for this site for this research project

Title	
Surname	
Forename	
Mailing Address	
Suburb /City	
Postcode	
Country	
Organisation name	
Department	
Email	
Phone (BH)	
Mobile	

** The PI will be responsible for ensuring there is a Contact Person at the site who will liaise with the low risk review personnel.*

9.4 How many Participants at this site

What is the proposed number of participants to be recruited at this site?

--

9.5 Provide the anticipated start and finish dates for the research project at this site.

9.5.1 Start date * / /
9.5.2 Finish date # / /
9.5.3 Duration (months):

* Start date refers to the first point of recruitment i.e. the date when the advertising or screening for participants begins.
Finish date refers to when no further contact with participants/data source is foreseen including the data analysis and reporting period.

9.6 Queensland Health policy on access to confidential information held by the Department.

9.6.1 Does the project require access to Confidential Information held by Queensland Health?
 Yes No

9.6.2 If so, have you consulted with the data custodian to determine whether the data you require is collected and accessible?
Yes No

Details of the *Public Health Act 2005* research provisions for access to confidential information may be found on the Queensland Health Research and Ethics Advisory Unit site

http://www.health.qld.gov.au/ohmr/html/regu/aces_conf_hth_info.asp. Application process and forms are available on this site.

For use of human tissue that is held by Queensland Health – Contact Research Office in Clinical and Statewide Services or visit

http://qhops.health.qld.gov.au/qhcss/research/research_home.htm

9.7 Intellectual Property considerations

9.7.1 Is there a possibility of new Intellectual Property to be developed from this project?
 Yes No

9.7.2 Has a search of patent databases been undertaken?
 Yes No

Step by step assistance on searching patent databases is available in IP Fact sheet 1 titled "*Information for Medical Researchers*" at:

http://www.health.qld.gov.au/ohmr/html/rcpu/intel_prop.asp

9.7.3 Does the contract state arrangements for the use of existing intellectual property and the parties' rights in relation to ownership?
 Yes No N/A

9.7.4 Does the contract state arrangements for the use of all new intellectual property developed through the research project? Yes No

N/A

If the answer is 'yes' to 9.7.1 and 'no' to 9.7.2 and/or 9.7.3 and/or 9.7.4 then you should take the following steps:

- (i) Discuss the issue of incorporating intellectual property terms in the contract with your associates and any legal or business manager assisting with development of the contract; and
- (ii) *Contact the Intellectual Property Unit within the Office of Health and Medical Research by emailing ip_officer@health.qld.gov.au to determine if the terms are suitable for Queensland Health.*

9.8 Study agreement

9.8.1 Is there a written research contract, signed by all relevant parties attached? Yes
No

If No, please give an explanation

If yes, name of organisation entering into contract with Qld Health (University, Collaborative group name etc)

9.8.2 Has the study agreement been reviewed and approved by an approved Qld Health legal team / District Lawyer? Yes
No

If yes, please complete

Name of legal team	Reviewed by (lawyer name)	Date reviewed	Reviewed for: Institution / District name

If no, the agreement will need review by the District Lawyer relevant to your District. If your district does not have a District Lawyer, please refer to the Research Management Policy and Framework http://www.health.qld.gov.au/ohmr/documents/res_man_pol_fram08.pdf

A written undertaking should be obtained from the sponsor to pay for any legal fees incurred by Queensland Health for review of non-standard contracts.

NOTE: For Qld Health – the delegated authority to sign ALL contracts is the responsibility of the District CEO or delegate.

9.9 Resource and Budget Information

Instructions for researchers:

Districts may incur costs in providing support for your research over and above those cost associated with standard care. Any costs over and above routine care which are to be met by the District are to be clearly identified and detailed. This includes both the 'Actual' costs and 'In kind' support. Confirmation of cost estimates, and agreement as to a funding source, is to be provided by the Director of Finance (or equivalent) in the first instance before final authorisation by the District CEO or delegate.

9.9.1 Has this protocol received research funding (including the researcher receiving any remuneration and/or in kind funding to perform this research) or is this submission being made as part of an application for research funding?

Yes No

If yes, please complete details applicable for this site

<i>Type of funding</i>	Source and type of funding	Amount (either \$/year OR \$/participant)	Approved or sought
Overseas Sources			
Business (commercially sponsored)			
Private non-profit organisations (eg collaborative groups)			
Donations/Bequests			
Australian Government eg NHMRC			
Joint Business/ Non Qld State Government			
Non Qld State/Local Government			
University			
Other Qld Govt Department eg Treasury			
Internal institutional competitive research grants			
Internal department funds			
Other Australian Sources			

9.9.2 Will participants receive any payment or expenses for participation in the research?

No

Yes

If yes, give details.

9.9.3 Departments and services involved in research *

List the departments/locations involved in the research at this site.

Department/location (e.g. Pathology, Allied Health)	Name of responsible person

* Note: A signed Declaration from the Head of Department must be attached with a completed SSA before Authorisation (see Declarations).

9.9.4. Study Budget - at this site

Item/s	Monetary cost for the site	Funds source (Cost centre)	Cost covered by sponsor (Y/N)
Diagnostics -imaging			Yes <input type="checkbox"/> No <input type="checkbox"/>
Diagnostics - pathology			Yes <input type="checkbox"/> No <input type="checkbox"/>
Diagnostics - other			Yes <input type="checkbox"/> No <input type="checkbox"/>
Principal Investigator			Yes <input type="checkbox"/> No <input type="checkbox"/>
Associate investigator(s)			Yes <input type="checkbox"/> No <input type="checkbox"/>
Clinical study coordinator			Yes <input type="checkbox"/> No <input type="checkbox"/>
Administrative support			Yes <input type="checkbox"/> No <input type="checkbox"/>
Other Infrastructure e.g. computers, printing, office space, stationary etc.			Yes <input type="checkbox"/> No <input type="checkbox"/>
Use of equipment			Yes <input type="checkbox"/> No <input type="checkbox"/>
Other (please state)			Yes <input type="checkbox"/> No <input type="checkbox"/>

If costs are not covered by the sponsor please explain how the costs will be covered or explain how the institution will benefit from the research

--

9.9.5. Finance Authorisation

Costs allocations and sources have been agreed:

.....	/ /
<i>Director of Finance/ Department Business Manager or equivalent name</i>	<i>Director of Finance/ Department Business Manager or equivalent signature</i>	<i>Date</i>
.....	/ /
<i>Principal Investigator name</i>	<i>Principal investigator signature</i>	<i>Date</i>

9.10. Funds Management Details

Identify the external organisation that will receive and manage the funding for this study if funds are not being managed by Queensland Health. Where the research is funded, Queensland Health has a responsibility to recover cost associated with research conducted at its facilities. Please provide details for invoicing.

Organisation Name	
Details of Contact Person	
Title	
First Name	
Surname	
Position	
Department	
Mailing Address	
Suburb / City	
State	
Postcode	
Country	
Business Phone	
Mobile Number	
Email	
Phone (BH)	
Fax	
External Administering Organisation Account Details	

If Queensland Health is the administering organisation provide details about the account number(s)/cost centre details into which funds are to be deposited.

QH Cost Centre # and / or internal Order Number (Insert number in Table)

--	--	--	--	--	--

a. Declaration by the Principal Investigator/Site Coordinator (s) and Associate Investigator(s) at this site

Project Title (in full):

Principal Investigator/Site Coordinator (s):

I/we certify that:

- All information is correct and complete as possible;
- I/we have had access to and read the NHMRC "*National Statement on Ethical Conduct in Human Research*" (2007)
 - The research will be conducted in accordance with the National Statement;
- I/we have consulted any relevant legislation and regulations, and the research will be conducted in accordance with these;
- I/we will immediately report to the HREC/Non-HREC review body anything which might warrant review of the research, including:
 - Serious or unexpected adverse effects on participants;
 - Complaints;
 - Proposed changes in the protocol; and
 - Unforeseen events that might affect continued ethical acceptability of the project;
- I/we have attempted to identify all the risks related to the research that may arise in conducting this research and acknowledge my obligations and the rights of participants;
- I/we will not continue the research if ethical approval or site authorisation is withdrawn and will comply with any special conditions required by the HREC/Non-HREC review body, including:
 - Conditions of approval stipulated by the HREC/Non-HREC review body;
 - Cooperate with monitoring requirements. At a minimum annual progress reports and a final report will be provided to the HREC/Non-HREC review body.
- I/we have the appropriate qualifications, training, experience and facilities to conduct the research set out in the attached application and to deal with any emergencies and contingencies related to the research that may arise;
- This project complies with the Queensland Health guidelines for submission for Low Risk Research review.

Researcher name	Designation	Signature	Date

Designation means designated title related to the project eg Coordinating Principal Investigator, principal investigator, co investigator, student, study coordinator, site sponsor if principal researcher not a QHealth employee etc

- b. **Declaration by delegated Department Head/s at the site where the Principal Investigator/Site Coordinator will conduct the research for the purpose of resourcing the research project.**

<p>Project Title (in full):</p> <p>Principal Investigator/Site Coordinator:</p>
--

I certify that I have read the project details in this SSA for the research project application named above.

I certify that I have discussed this research project and the resource implications for this Department, with the Principal Investigator/Site Coordinator.

I certify that there are suitable and adequate facilities and resources for the research project to be conducted at this site. This is for 'Actual costs' and 'In kind' contribution.

My signature indicates that I support this research project being carried out using such resources.

<p>Name of Department.....</p> <p>Name of Head of Department</p> <p>Signature Date:.....</p>
--

** Where an investigator is also Head of Department, certification must be sought from the person to whom the Head of Department is responsible. Investigators must not approve their own research on behalf of their Department.*

c. Declaration by Head of Supporting Department at this site

This form is to be completed by the Head of any Department that is providing support or services to the research project, but which does not have any member(s) on the research team.

<p>Project Title (in full):</p> <p>Principal Investigator (s) or Contact person (at this site):</p>
--

I have discussed this project with the Principal Investigator and have read the research project.
I am: (*tick whichever applies*)

- able to perform the investigations/services indicated, within the present resources of the Department;
- able to perform the investigations/services indicated, if the following financial assistance is provided

- unable to undertake the investigations/services indicated, on the following grounds:

<p>Name</p> <p>Department Position</p> <p>Signature Date:.....</p>

Office Use Only

Project Title.....

Principal investigator.....

Accepted for Low Risk Review

Yes

No

Low risk review AU RED Number:.....

Allocated to:

Low Risk Review panel

Yes

No

or

Designated HREC members:

1.....

2.....

SF17: Annual/Progress Report Form

**HUMAN RESEARCH ETHICS COMMITTEE
ANNUAL REPORT FOR RESEARCH PROTOCOLS**

PROTOCOL NO.

PROTOCOL TITLE:

PRINCIPAL INVESTIGATOR:

Information Required	Response	Comments
No. of patients recruited to date	Locally: Other Sites:	
No. and Nature of Serious Adverse Events at this site		
Have all Serious Adverse Events been reported to the HREC?		
Has the principal investigator reviewed and reported all SAEs to the HREC?		
Where necessary, have changes been made to the Patient Information and Consent Form, e.g. additional risks, change of investigators?		
Is all trial related data being stored according to Good Clinical Practice?		
Difficulties encountered, e.g. recruiting, if any		
Results to date, if any		
Please attach a copy of the latest version of the Patient Information and Consent Form		

.....
Signature of Principal Investigator

.....
/ /

Date

Please forward to the HREC at specified reporting time frames as required under conditions of approval for the project.

SF18: Final Report Form

**HUMAN RESEARCH ETHICS COMMITTEE
FINAL REPORT FOR RESEARCH PROTOCOLS**

PROTOCOL NO.

PROTOCOL TITLE:

PRINCIPAL INVESTIGATOR:

Information Required	Response	Comments
No. of patients recruited	Locally: Other Sites:	
No. and Nature of Serious Adverse Events at this site		
Were all Serious Adverse Events reported to the HREC?		
Where, how and for how long is trial related data being stored?		
Difficulties encountered during the study, if any, e.g. recruiting		
Results to date, if any		
Is data analysis complete?		
Are final results attached?		
If results are not attached, when will they be available?		

.....
Signature of Principal Investigator

...../...../.....
Date

Please forward to HREC at completion of study

SF19: SAE Report – local

QUEENSLAND HEALTH RESEARCH AND ETHICS UNIT

REPORT OF LOCALLY OCCURRING ADVERSE EVENT TO HREC

Protocol No.
Protocol Title:

Patient (<i>Initials or Record No. only</i>)	Date of Birth	/ /	
	Gender	M	F
	Weight	Kg	
Adverse Reaction Description	Date of Onset of Reaction	/ /	
	Severity:	Yes	No
	Serious Life threatening Expected	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>

All Drug Therapy/Vaccines Prior to Reaction	Daily Dosage	Date Begun	Date Stopped	Reason for Use

Previous Medical History:

Treatment of reaction:

Outcome:

	Yes	No
Do you consider the event to be related to the study intervention?	<input type="checkbox"/>	<input type="checkbox"/>
Has the study sponsor been notified?	<input type="checkbox"/>	<input type="checkbox"/>
In the light of the event, is a change required to the Participant Information Sheet?	<input type="checkbox"/>	<input type="checkbox"/>
If yes, will already enrolled patients be re-consented? If no, why not?	<input type="checkbox"/>	<input type="checkbox"/>
If yes, is the revised Participant Information Sheet attached?	<input type="checkbox"/>	N/A

_____/_____/_____
Name of Principal Investigator Signature of Principal Investigator Date

SF20: SAE Report – External

Date SAE reports noted and accepted by HREC: ___ / ___ / ___

Principal Investigator

Signature: _____

Name: _____

Title: _____

Date: ___ / ___ / ___

**HUMAN RESEARCH ETHICS COMMITTEE
EXTERNAL SERIOUS ADVERSE EVENTS REPORT**

HREC Protocol No.: ___ / ___

Protocol Title: _____

Date Submitted to HREC: ___ / ___ / ___ Submitted By: _____

SERIOUS ADVERSE EVENT (Type of Event)	Control/Patient ID No	DATE OF EVENT	SUSPECTED AGENT	IS CAUSALITY SUSPECTED? (e.g. possible, probable, unlikely, etc)	SITE WHERE EVENT OCCURRED (e.g. PAH, RBHSD, QEII, elsewhere in Australia, Overseas country)	INITIAL OR FOLLOW UP REPORT	INVESTIGATOR'S SUMMARY AND COMMENTS
<i>For example: Atrial Thrombosis</i>	<i>ABCDE2010101</i>	<i>25/08/2008</i>			<i>Overseas & Australia</i>	<i>Initial</i>	<i>Non related</i>

SF21: Fees for review of commercially sponsored research by Human Research Ethics Committees and Governance Review (Site Specific Assessment)

**Schedule of Fees for Ethics and Research Governance
Review of Commercially Sponsored Research**

1. The following fees apply to all applications to review commercially sponsored research made to all Queensland Health Districts, commencing 17 October 2008. That is, it applies to all HREC applications and all site specific assessment applications lodged with a Queensland Health District/Site after 17 October 2008. Fees are applicable to both Single & Multi-site Industry Sponsored Research

Table 1: Fees for review of commercially sponsored research by Human Research Ethics Committees and Governance Review (site specific assessments)

Fee	Value
HREC fees for application for research project with full industry sponsorship	\$3300
HREC fees for amendments to research projects with full industry sponsorship*	\$550
HREC fees for addition of sub-studies to research projects with full industry sponsorship#	\$1665
Independent Review Fee	Cost Recovery Only
Site-Specific Assessment (SSA) Fee	\$3300 per site

* Amendments include changes to the protocol excluding minor administrative changes

Sub-studies will be reviewed and fees determined on a case-by-case basis. The HREC may request that the sub-study be submitted as a new application and charge the full fee.

All figures are inclusive of GST.

SF22: Membership Selection Criteria

Process for Appointing Committee Members

General Criteria:

1. experience of a broad range of community activities
2. able to understand/learn and apply research ethics principles
3. interest in health and health research issues
4. able to read and understand QH HREC application documents
5. able to appreciate the interests of potential research participants and the potential risks and benefits of research proposals, and to assess the balance between the two
6. able to actively participate in and contribute to Committee discussions on research proposals and other research ethics issues
7. able to attend meetings and able to participate in and respond to delegated HREC applications when required.

Specific Criteria:

Lay Member:

1. interest in and awareness of health consumer issues
2. not involved in health research or health services delivery
3. not directly associated with Queensland Health services or research
4. not a lawyer or Minister of Religion (or equivalent)

Member with Legal Experience:

1. legal qualifications and experience in the practice of law
2. interest in and knowledge of legal issues to health services or health research is desirable

Member with pastoral care experience:

1. experience as a minister of religion, spiritual leader or Aboriginal elder
2. interest in and knowledge of religious or spiritual issues relevant to health services or health research is desirable

Members with knowledge of and current experience in the professional care/counselling and treatment of people:

1. experience in the delivery of health or community services
2. particular experience of service delivery in a hospital setting or a community setting, depending on the vacancy being filled

Members with health research experience:

1. experience in the conduct of health research
2. experience in clinical, social science, epidemiological or laboratory research, depending on the vacancy being filled.

SF23: Expression of Interest for HREC Members



EXPRESSIONS OF INTEREST:

The [Name] Hospital Health Service District has a Human Research Ethics Committee (HREC) composed of volunteers and administered by a small secretariat. People from a variety of walks of life are invited to consider becoming a member of the Committee. The purpose of the role is to assist in fulfilling the institutional requirement for a properly constituted and functioning Human Research Ethics Committee, and to thereby ensure that all research has merit, is just, has risks commensurate with the potential benefit, and indicates respect for participants.

The membership categories include:

- Lay men and women, who have no affiliation with the institution and do not currently engage in medical, scientific, legal or academic work;
- Persons with knowledge of, and current experience in, the professional care, counselling or treatment of people; for example, a nurse or allied health professional;
- A person who performs a pastoral care role in a community, for example, an Aboriginal elder, a minister of religion;
- People with current research experience that is relevant to research proposals to be considered at the meeting they attend.

The HREC is seeking interested people who fulfil one of these categories to become a member of the Committee.

Members are asked to consider research against international and national guidelines on ethical research conduct, and on the basis of their own knowledge, qualities and experience and not as representatives of any organisation, group or decision.

ENQUIRIES: [Phone]

APPLICATIONS TO: [Insert full name and address]

SF25: Agreement to enter personal contact details on INFONETICA AU – RED for HREC Members:

Agreement to enter personal contact details on the INFONETICA Australian Research Ethics Database (AU – RED)

I _____ agree to allow the following personal contact details to be stored on the INFONETICA Australian Research Ethics Database (AU – RED). AU – RED is an online application system for managing research ethics applications that is maintained by QH HRECs.

Privacy Notice:

Confidential personal information that is stored in the AU – RED application in the United Kingdom is protected by British Privacy Legislation – the Data Protection Act 1998 (UK). Confidential personal information that is stored by Queensland Health is protected by the Departments Information Standard 42A (Privacy).

- Name Postal Address Courier Address Email
 Home Phone Work Phone Mobile Fax

Alternate Contact:

- Name Postal Address Courier Address Email
 Home Phone Work Phone Mobile Fax

Signature

Date

Please complete the details below:

HREC Member Contact Details

Name
Postal Address
Courier Address
Phone (H)
Phone (W and/or Mobile)
Fax
Email:

Alternate Contact Details

Name
Postal Address
Courier Address
Phone (H)
Phone (W and/or Mobile)
Fax
Email:

XXXXXXXXXXXXX
Human Research Ethics Committee
ECXXX

Terms of Reference

INTRODUCTION

Preamble

The XXXXXXXXXXXXXXXX Human Research Ethics Committee [ECXXX] is a committee established by XXXXXXXX (XXXXXXXX), Queensland Health (QH) that is constituted and functions in accordance with the NHMRC 'National Statement on Ethical Conduct in Human Research' (2007) - the National Statement (NS); and complies with the 'Australian Code for Responsible Conduct of Research (2007) and QH Research Management Policy and Framework (QHRMP; 2008).

HREC objectives

- Protect the mental and physical welfare, rights, dignity and safety of participants of research
- Facilitate ethical research through efficient and effective review processes
- Promote ethical standards of human research
- To ensure that all clinical and health research is conducted ethically and responsibly

HREC functions and responsibilities

- Provide independent, competent and timely review of research projects in respect of their ethical acceptability
- Monitor approved research studies for which the HREC has given approval and provide advice at any time to the relevant District XXXXXXXXef Executive Officer (DCEO), through the XXXXXXXX, and coordinating principal investigator, when the HREC considers that ethical approval for research should be withdrawn
- Obtain expert opinions (external or internal) as required to provide scientific/technical assessment on human research protocols and evaluation of research clinical trials/studies and compliance with regulatory requirements
- Register on the Australian Research Database (AU RED) all research applications submitted to the HREC, any monitoring and reporting requirements and any ongoing approval status of proposals including amendments
- The XXXXXXXXXXXXXXXX Human Research Ethics Committee will undertake ethical review in the following research fields:
 - XXXXXXXX
 - XXXXXXXX
 - XXXXXXXX

Relationships and reporting

The XXXXXXXXXXXX Human Research Ethics Committee will:

- Report and be accountable to the XXXXXXXXef Executive Officer of the XXXXXXXX by:
 - Tabling of all amendments to the XXXXXXXXXXXXXXXX HREC Terms of Reference at the XXXXXXXX executive management meeting
 - Tabling of XXXXXXXXXXXXXXXX HREC monthly meeting minutes at the XXXXXXXX executive management meeting
 - Tabling of XXXXXXXXXXXXXXXX HREC NHMRC annual report for institutions with a Human Research Ethics Committee at the XXXXXXXX executive management meeting annually.
 - Tabling of XXXXXXXXXXXXXXXX HREC list of HREC members and their associated National Statement on Ethical Conduct in Human Research categories of research at the XXXXXXXX executive management meeting annually.
- Submit a report annually to the National Health and Medical Research Council (NHMRC) and the Australian Health Ethics Committee to maintain accreditation and registration as a compliant human research ethics committee.
- Liaise with Queensland Health Service Districts, Universities, other research facilities and research personnel as appropriate.
- Process the charging of fees to the sponsors of commercial research, as per the QH Research Management Policy, both for the processing (initial application and amendment submissions) and consideration of the protocols.
- Acknowledge that the District CEO of individual Health Service Districts will have the right to not approve the conduct of a research project within its District.
- Make public the membership of the HREC on the QH Research Ethics and Governance Unit website.

1. HREC ESTABLISHMENT

1.1 HREC Composition

- The HREC membership appointment will be constituted in accordance with the National Statement and will include the following:
 - (a) a chairperson, with suitable experience, whose other responsibilities will not impair the HREC's capacity to carry out its obligations under this National Statement;
 - (b) at least two lay people, one man and one women, who have no affiliation with the institution and do not currently engage in medical, scientific, legal or academic work;
 - (c) at least one person with knowledge of, and current experience in , the professional care, counselling or treatment of people; for example, a nurse or allied health professional;
 - (d) at least one person who performs a pastoral care role in a community, for example, an Aboriginal elder, a minister of religion;
 - (e) at least one lawyer, where possible one who is not engaged to advise the institution; **and**
 - (f) at least two people with current research experience that is relevant to research proposals to be considered at the meetings they attend. These two members may be selected, according to need, from an established pool of inducted members with relevant expertise.
- The minimum membership of an HREC is eight.
- As far as possible there will be equal numbers of men and women.
- At least one third of the members will be from outside the institution for which the HREC is reviewing research.
- At any one time, at least half the members appointed in the minimum membership categories listed under the National Statement (5.1.30) will have two or more years experience on a HREC.
- Annually the HREC Chair will assess the categories and quantities of research received and align, as required, the expertise of the committee with the research studies received for review.

1.2 HREC appointment of members

- The CEO of the XXXXXXXX or delegate shall appoint members of the HREC, in consultation with the HREC and other senior Health Service officials, as deemed appropriate.
- Membership appointments to the HREC will be considered for review every three years.
- Prospective members of the HREC may be recruited by direct approach, nomination or by advertisement.
- Appointments will allow for continuity, the development of expertise within the HREC, and the regular input of fresh ideas and approaches.
- Members are appointed for a period of three years and may serve two consecutive terms only unless otherwise approved by the CEO of XXXXXXXX or delegate
- The Chairperson and members may serve longer terms with the approval of the XXXXXXXXef Executive Officer of XXXXXXXX or delegate.
- Reappointment is by application to the Chairperson of the HREC who will then make a recommendation to the XXXXXXXX Executive Officer of XXXXX or delegate.
- Membership will lapse if a member fails without reasonable excuse or without notifying the Chairperson to attend three consecutive meetings of the HREC, unless exceptional

circumstances exist. The Chairperson in writing will notify the member of such lapse of membership. Steps shall be taken to fill the vacancy of the lapsed member.

- A member may resign from the HREC at any time upon giving notice in writing to the Chairperson. Steps shall be taken to fill the vacancy of the former member.
- The XXXXXXXX Executive Officer of XXXXX or delegate may terminate the appointment of any member of the HREC if the CEO is of the opinion that:
 - it is necessary for the proper and effective functioning of the HREC;
 - the person is not a fit and proper person to serve on an HREC;
 - the person has failed to carry out their duties as an HREC member.
- Members will be provided with a letter of appointment which will include date of appointment, length of tenure, assurance that indemnity will be provided in respect of liabilities that may arise in the course of bona fide conduct of their duties as a HREC member, HREC meeting attendance responsibilities and general responsibilities as a HREC member.
- Members are not offered remuneration. However, members will be reimbursed for legitimate expenses incurred in attending HREC meetings or in otherwise carrying out the business of the HREC.
- Members will be required to sign a statement undertaking:
 - that all matters of which he/she becomes aware during the course of his/her work on the HREC will be kept confidential;
 - that any conflicts of interest, which exist or may arise during his/her tenure on the HREC will be declared; and
 - that he/she has not been subject to any criminal conviction or disciplinary action, which may prejudice his/her standing as a HREC member.
- A small gift of appreciation, not above the QH reportable threshold, may be made to HREC members each year in recognition of the very substantial time commitment and intellectual input they make to Queensland Health. Refer to FMPM Circular No. 4/2010 Giving & receiving of Gifts & benefits for advice:
http://qheps.health.qld.gov.au/finance/sfs/fmpm/documents/circulars/gifts_policy.pdf
- The Director, Research Ethics and Governance Unit, Office of Health & Medical Research or delegate will attend the HREC meetings, as required, as an observer. The role of the Director, Research Ethics and Governance Unit will be as a non voting, HREC Advisor regarding the regulation of and access to Queensland Health databases and collections.

1.3 Education for HREC members

- Newly appointed members shall be provided with adequate orientation, induction and mentoring.
- Throughout their tenure, members shall be given the opportunity to attend conferences and workshops relevant to the work and responsibilities of the HREC, at the expense of the Centre for Health Care Improvement.
- Members will attend continuing education and training in research ethics at least every two years.

1.4 HREC Sub-committees

- The HREC may appoint such sub-committees as it sees fit to carry out a scientific or technical review of a research proposal, or ethical review of minimal risk research, submitted to the HREC.

- The Chair of any such subcommittee will be appointed by the XXXXXXXX Executive of XXXXXXXX.
- Members of the subcommittee need not be members of the HREC.

1.5 HREC Liability coverage

- QH provides indemnity for members of the HREC for any liabilities that arise as a result of the member exercising his or her duties as a member in good faith. Indemnity is provided through Queensland Government Insurance Fund (QGIF) in accordance with HR Policy I3.
- QH provides indemnity for external expert reviewers for any liabilities that arise as a result of the reviewer exercising his or her duties in good faith. Such indemnity is provided through Queensland Government Insurance Fund (QGIF) in accordance with HR Policy I3.

1.6 National certification for multi centred ethical review

- Where an institution elects to nominate for certification the following will occur:
 - Institution undertakes self assessment
 - Institution nominates to be assessed for certification by submitting paper work to national certification body
 - Certifying body undertakes desk top audit of institutional paper work
 - Certifying body conducts an onsite visit and issues draft report
 - Certifying body issues final report and, if approved, certification conditions
- Certification standards will be as per the Australian national certification standards.
- The responsibility for meeting these certification standards rests with the XXXXXXXX

2. HREC PROCEDURES

2.1 Standard operating procedures

- The HREC will perform its functions in accordance with the *National Statement on Ethical Conduct in Human Research* (2007) - the *National Statement (NS)*, the *Australian Code for Responsible Conduct of Research (2007)* and *QH Research Management Policy and Framework (QHRMP; 2008)* and all subsequent updates.
- The HREC will perform its functions, including monitoring of research and handling of complaints, according to written standard operating procedures (SOP) accessed from the QH Research Ethics and Governance Unit (REGU) website. These procedures shall be reviewed at least every three years and amended and updated as necessary.
- All HREC members shall have access to and/or be provided with copies of the SOP and shall be consulted with regard to changes thereto.
- All issues involving research governance will be dealt with in accordance with the QH Research Governance Standard Operating Procedures, accessed from the REGU website.

2.2 Submissions

All Studies

- The HREC will consider every application which it receives, at its next available meeting following receipt, provided that the application is valid and received by the relevant closing date.
- When a submission, including amendments, is accepted by the HREC, the HREC administrator will continue the process of HREC review and approval as per the HREC SOP.
- Research involving access to coronial material must be referred to the Queensland Health Forensic and Scientific Services Human Research Ethics Committee (FSS-HEC) for ethical and legal approval.
- The District CEO or Delegate is the person to grant authorisation of research projects on humans to be conducted within or in association with QH Districts.

Single Site Studies

- All submissions of all single site studies, for review by the HREC, will be made directly to the reviewing HREC.

Multi-centre Research Studies

- From 1 July 2010 the submission of all multi-centre research studies being submitted through the single ethical review process, for review by a HREC, will be through the QH Central Coordination Service (CCS) as per the QH HREC SOP.
- For multi-centre research studies an HREC, that has been assessed and certified under the national certification scheme, will be the single HREC body to conduct the ethical-scientific review of the 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 single ethical review process.

2.3 Meetings

General

- Meetings will be held in accordance with QH HREC SOP
- The HREC agenda, accompanied by all required documentation for review of research proposals will be distributed not later than 5 working days prior to the HREC meeting.
- Decisions by the Committee about whether the research project meets the requirements of the National Statement will be informed by the exchange of opinions from each of the members that constitute the minimum membership of the HREC.
- In line with the National Statement Sections 5.2.28 - 5.2.31 there is no quorum for HREC meetings. Where there is less than full attendance of the minimum membership at a meeting, the Chairperson must be satisfied, before a decision is reached, that the views of those absent who belong to the minimum membership has received all papers and have had an opportunity to contribute their views and that these have been recorded and considered.
- The contribution of information and opinion from a committee member unable to attend a face to face meeting will be considered along with those opinions and feedback of other committee members in the final decision making.
- Members who are unable to attend a meeting will be encouraged to contribute and advise their opinion via submission to the HREC Administrator prior to the meeting.
- In general, decisions of the HREC will be reached by general agreement and consensus.

- Members of the committee will be required to declare any conflict of interest prior to or at any time during a meeting. The Chairperson will determine the action to be taken.

Dates and venue

- Meetings will be held monthly except for December or January when no meetings will be held.
- Meeting dates will be available on the Research Ethics and Governance Unit website.
- Meetings will normally be held at on XXXXXX on the XXXXX of every month with the exclusion on January and December between XXXXXX am.

Secretarial Support

- Secretarial support will be provided by the Ethics Administrator XXXXXXXXXX

Decisions from HREC meetings

- The minutes of meetings will be recorded on AU RED.
- Minutes will record major issues discussed, concerns expressed, decisions taken and reasons for rejection or requirement for change to the protocol, linking those reasons to the National Statement.

2.4 Conflicts of Interest

- Members will be required to sign a statement undertaking that any conflicts of interest, which exist or may arise during his/her tenure on the HREC, will be declared.
- HREC members will be required to declare any conflict of interest prior to or at any time during a HREC meeting. The Chairperson will determine the action to be taken. (National Statement section 5.2.4; Chapter 5.4)
- All conflicts of interest will be managed as per Research Management Policy and Framework 2010 Implementation Standard 5: Conflicts of Interest in Research

2.5 Monitoring

- Monitoring of research given institutional authorisation will be as per QH HREC & RGO SOP Version 3 Section: HREC monitoring of research given institutional authorisation (Appendix A).

2.6 Complaints

- Research complaints concerning the conduct of a project and / or a HREC's review process, including the HREC's rejection of an application should be managed as per the QH HREC SOP.
- The 'Advisor in Research' applicable to this committee is XXXXXXXX
- The 'Designated Person' applicable to this committee is XXXXXXXXXX

2.7 Access to External Expert reviewers

- The HREC may seek the written advice of an external 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.
- The QH Panel of External Expert Reviewers can be accessed at any time by the HREC, by contacting the QH Research Ethics and Governance Unit.

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

3. AMENDMENT TO THE TERMS OF REFERENCE

These Terms of Reference may be amended by following the procedure below:

For those proposals made by a HREC member:

- The proposal must be in writing and circulated to all HREC members for their consideration.
- The views of the members should be discussed at the next scheduled meeting of the HREC, and a vote taken at that meeting. Any member unable to attend such a meeting may register his or her views in writing.
- The proposal shall be ratified if two thirds of the members agree to the amendment.

For those proposals made by the XXXXXXXX Executive:

- The XXXXXXXX Executive will send the proposal to the HREC and seek the views of any relevant person.

All amendments of the XXXXXXXXXXXXX HREC Terms of Reference will be tabled at a XXXXXXXX executive management meeting

Appendix A: HREC MONITORING OF RESEARCH GIVEN INSTITUTIONAL AUTHORISATION

General Policy on monitoring of research

- Research should normally commence within 12 months of the date of ethical approval.
- Should the study not commence within 12 months, the Principal Investigator (single site studies) or Coordinating Principal Investigator (CPI) (multi-centre studies) is required to provide the HREC with a written explanation for the delay.
- Should the project not commence within 24 months, the matter will be discussed at a meeting of the HREC. At the discretion of the HREC, the approved ethical decision may be suspended and the Principal Investigator / CPI required to submit a new application once the problems relating to the delay of the study have been fully addressed.
- To allow monitoring to occur, the HREC Chairperson or delegate may decide to allow other persons access to HREC application 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. This may include random inspections of research sites, data, or consent documentation and interviews with research participants or other forms of feedback from them.
- All reports will be tabled at an HREC meeting and reviewed by the committee.
- All reports should be on the standard template accessed from the REGU website.

Duration of an approved ethical decision

- The approved ethical decision of the main HREC applies for the expected duration of the research as specified in the approval letter, except where action is taken to suspend or terminate the decision.
- Where the Principal Investigator / CPI proposes to extend the duration of the study, for example to allow more time for recruitment of participants, this must be submitted for review to the HREC.

Progress reports

- Progress reports on all research given an approved decision should be submitted to the HREC at least annually, or more frequently if the level of risk is assessed by the HREC to so indicate. The first Annual Report should be submitted 12 months after the date on which ethical approval was given.
- Reports must be submitted by the Principal Investigator (or CPI for multi-centre studies) and signed.
- Annual reports should be accompanied by the reporting letter from the Data Safety Monitoring Board, if applicable.
- Where a progress report is not received by the due date, the HREC Administrator will send a reminder letter. If the report is still not received after a further period of one month, the matter will be considered at the next meeting of the HREC.

Final Reports

- A final report on all research given District authorisation should be submitted to the HREC at completion of the research and should include a copy of the final published results.

Urgent Safety Measures

- The Coordinating Principal Investigator, or a Site Principal Investigator 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. The HREC must be notified immediately and in any event within 3 days that such measures have been taken. The notice should set out the reasons for the urgent safety measures and the plan for further action. QH policy is that these requirements should apply to all research with an approved decision from a HREC and authorisation by the District CEO or Delegate of the QH District.
- Notifications of urgent safety measures should be reviewed at a 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. Where any concern arises about the safety or welfare of participants or the conduct of the research, the HREC should address these with the Principal Investigator in writing.

Early Termination of Study by the Principal Investigator

- Where a research project is terminated or suspended by the Principal Investigator / CPI prematurely, the HREC must be promptly informed and provided with a detailed written explanation of the circumstances, having regard to the ongoing safety and welfare of any research participants who may be receiving study treatment.

Suspension or Withdrawal of HREC Approval

- The HREC may suspend or withdraw its ethical approval 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.
- Where the HREC considers it appropriate that the adverse event/s and/or monitoring reports requires the immediate suspension or discontinuation of the ethical approval of the research project, the HREC should immediately notify the Coordinating Principal Investigator (or Site Principal Investigator for single site studies).
- An Investigator cannot continue with the research if ethical approval has been suspended or withdrawn and must comply with any special conditions imposed by the HREC or district/site Research Governance Office/r.

HRECs and Adverse Event Reporting in Australian for Clinical Trials

- The Principal Investigator / CPI must capture and report AEs, including SAEs, which occur at their site to the sponsor in accordance with the study protocol. The Principal Investigator / CPI must report all SAEs to the sponsor immediately (within 24 hours of finding out about the event) in accordance with the study protocol and GCP guidelines as adopted by the TGA. The requirements for adverse event reporting to HRECs by Investigators will be in accordance with the Australian Health Ethics Committee (AHEC) Position Statement: Monitoring and reporting of safety for clinical trials involving therapeutic products MAY 2009 for reporting requirements.

http://www.nhmrc.gov.au/_files_nhmrc/file/health_ethics/hrecs/reference/090609_nhmrc_position_statement.pdf

Fully Sponsored Pharmaceutical or similar trials

- HRECs should be provided with a copy of the SAE notification as soon as possible and within a one month maximum time lapse;

- If the event is serious and unexpected and may affect other participants on the trial, the HREC and Institution must receive immediate notification (that is, within 24 hours of the investigator becoming aware of the event)

Non Sponsored Trials

- Non sponsored trials with only a local DSM Committee are required to immediately provide notification to the HREC within 24 hours of the investigator becoming aware of the event. If it is considered that the SAE is related to the study, immediate notification to the HREC and Institution administration is required.

Tracking of Medical Devices

- Tracking of medical devices is as per the TGA requirements and Australian Medical Devices Guidelines: Medical Device TGA SAE Forms and guidelines:
http://www.tga.gov.au/docs/pdf/forms/iris_mdir03b.pdf and
http://www.tga.gov.au/docs/pdf/forms/iris_udir03c.pdf
<http://www.tga.gov.au/docs/pdf/devguid11.pdf>
- Device identifiers are to be placed into patients medical notes and manufacturers are required to maintain a tracking system

SF27: General Principles of Handling Research Complaints

GENERAL PRINCIPLES OF HANDLING RESEARCH COMPLAINTS

STANDARDISED:

- Consistency in process and decision making;
- Enhance public and staff acceptance of process;

ACCOUNTABLE:

- Ensure people with appropriate experience and expertise provide guidance and advice on complaint cases;
- Complaint process is complete and demonstrates accountability by the Health Service District;

TRANSPARENT:

- Take appropriate steps to maintain public confidence in the research;
- Take appropriate steps to avoid conflicts of interest in managing complaint cases;
- Decide who should be informed and how.

ACCESSIBLE:

- Ensure appropriate personnel are identified and easily accessible for a complaint to be made;
- Informing the complainant of the complaint management process;

TIMELINESS:

- Acknowledgement of complaint, recorded and investigated in a timely manner in the best interest of all parties;
- Ensure prompt and effective response in each complaint case;

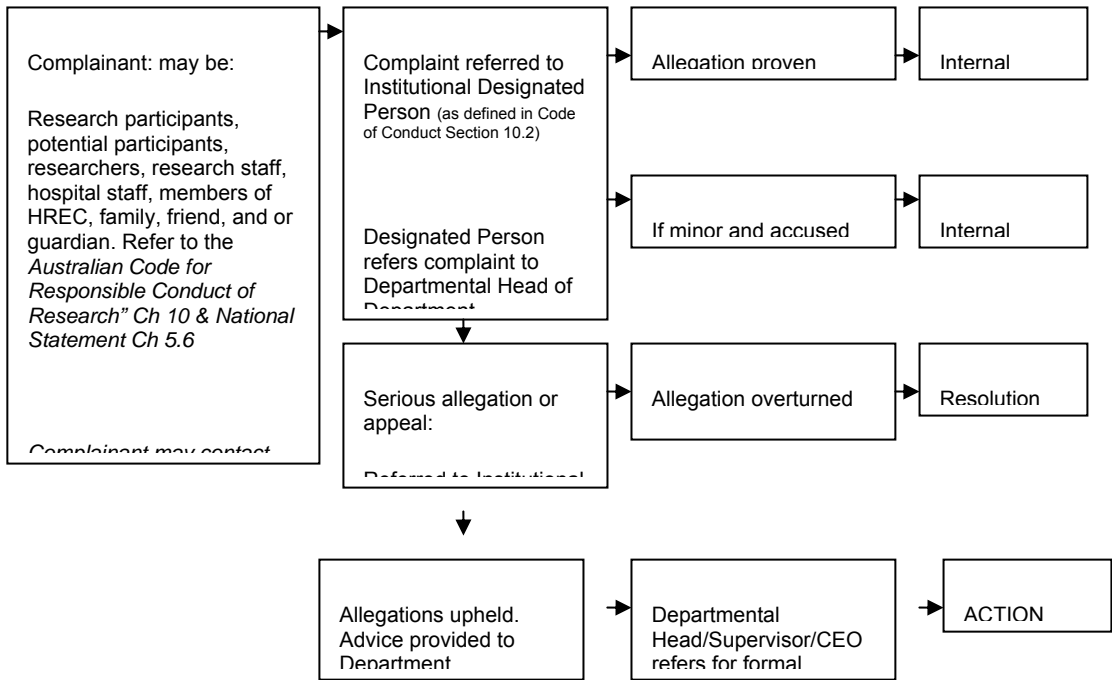
PROCEDURAL FAIRNESS:

- All affected parties must be treated in a way that supports natural justice;
- Allegations of research misconduct or complaints concerning a HREC/Review Body should be made in writing;
- Person facing allegations has a right to be heard;
- Personnel investigating complaint must be free from bias or preconception;
- Findings/Outcomes of complaint should be provided in writing and stating reasons for findings/outcomes;
- Person who makes allegations must be treated fairly;
- Provide an avenue for appeals.

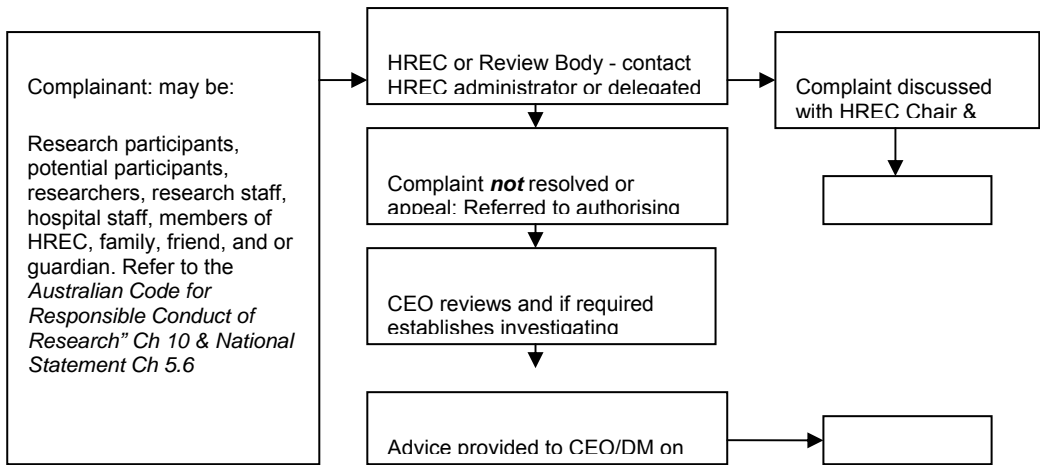
SF28: Research Complaints Process – HRECs and Research misconduct

Complaints concerning the conduct of a project including Research Misconduct

Research Misconduct including but not limited to examples listed in 10.1.1 "Australian



Complaints concerning the conduct of a project including Research Misconduct



SF29: Internet Student Orientation Package Checklist – Example Only



Internet Student Orientation Package Checklist

It is a requirement of Queensland Health that you review this internet orientation package **prior** to beginning your placement with Queensland Health. Information contained on the website may have medicolegal and Workplace Health and Safety implications. Before you sign this checklist, please ensure that you have read each of the essentials sections thoroughly. By signing the checklist you are indicating that the information contained on this website is understood. This checklist must be given to the appropriate contact person in your course and a copy must be given to your clinical/Student Liaison Officer supervisor on the first day of your placement.

(tick to indicate the areas that you have read and understood and agree to be bound by)

Student Expectations	<input type="checkbox"/> Professional behaviour & responsibilities <input type="checkbox"/> Code of conduct <input type="checkbox"/> Use of cars <input type="checkbox"/> Blue card <input type="checkbox"/> Professional boundaries <input type="checkbox"/> Professional appearance <input type="checkbox"/> Home visits
Confidentiality, Privacy and Documentation	<input type="checkbox"/> Confidentiality <input type="checkbox"/> Documentation <input type="checkbox"/> Privacy
Workplace Health and Safety	<input type="checkbox"/> Fire safety <input type="checkbox"/> Manual handling <input type="checkbox"/> Infection control <input type="checkbox"/> First aid <input type="checkbox"/> Incident reporting <input type="checkbox"/> Immunisation
Cultural Diversity	<input type="checkbox"/> Multicultural Awareness & Language Services <input type="checkbox"/> Aboriginal and Torres Strait Islander Health

I _____ certify that I have read and understood the essential information on the Queensland Health orientation website in preparation for my placement with Queensland Health.

I _____ certify that I have read and understood the sections specifically referring to confidentiality and privacy and I agree to abide by those principles and the Queensland Health Code of Conduct.

I understand that this orientation is one of the requirements of eligibility for a placement at a Queensland Health facility.

Signature: _____ Date: _____

Name:	Course:
Year:	Institution:

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