

The University of Queensland
**Human Research Ethics Committees: Standard Operating
Procedures**

To be reviewed by 30 June 2017

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1. BACKGROUND

1.1 About this document

This document provides standard operating procedures for The University of Queensland (UQ) Human Research Ethics Committees (HRECs), their subcommittees, and the Ethics Secretariat so that quality and consistency in ethical review and associated processes are maintained. This Guideline has been developed to provide standard operating procedures to ensure that the UQ HRECs are constituted and operate in accordance with the National Statement on Ethical Conduct in Human Research (2007) incorporating all updates.

1.2 Scope

The standard operating procedures apply to human research conducted at sites under the control of UQ; and/or involving, students, staff members, or formal appointees of UQ.

1.3 Abbreviations

CTN	Clinical Trial Notification
CTX	Clinical Trial Exemption
HREC	Human Research Ethics Committee
NEAF	National Ethics Application Form
NHMRC	National Health and Medical Research Council
SAE	Serious adverse event
SUSAR	Suspected unexpected serious adverse reaction
TGA	Therapeutic Goods Administration

1.4 Key definitions

Adverse event

For medicines, also referred to as an adverse experience, 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. An adverse event can therefore be any unfavourable and unintended sign, symptom, or disease temporally associated with the use of a medicinal (investigational) product, whether or not related to the medicinal (investigational) product.

For devices, any undesirable clinical occurrence in a subject whether it is considered to be device related or not, that includes a clinical sign, symptom or condition and/or an observation of an unintended technical performance or performance outcome of the device.

Clinical trial means any investigation in human subjects intended to discover or verify the clinical, pharmacological and/or other pharmacodynamic effects of an investigational product(s), and/or to identify any adverse reactions to an investigational product(s), and/or to study absorption, distribution, metabolism, and excretion of an investigational product(s) with the object of ascertaining its safety and/or efficacy. [Ref: Note for Guidance on Good Clinical Practice (CPMP/ICH/135/95): Annotated with TGA comments].

Data & Safety Monitoring Board is an independent data monitoring committee that may be established by the sponsor to assess at intervals the progress of a clinical trial, the safety data, and the critical efficacy points, and to recommend to the sponsor whether to continue, modify, or stop a clinical trial. [Ref: Note for Guidance on Good Clinical Practice (CPMP/ICH/135/95): Annotated with TGA comments].

Epidemiological research is the study of the distribution and determinants of health related states or events in specified populations, and the application of this study to the control of health problems.

Health services research is research involving the integration of epidemiologic, sociologic, economic and other analytic sciences to study health services.

Human research is research conducted with or about people, or their data or tissue as described in the National Statement on Ethical Conduct in Human Research (2007) incorporating all updates .

Human Research Ethics Committee (HREC) is a committee constituted in accordance with the National Statement on Ethical Conduct in Human Research (2007) incorporating all updates to review and where appropriate approve and monitor the ethical and scientific aspects of human research.

Investigator's brochure is a compilation of clinical and non-clinical data on the investigational product(s) relevant to the study of investigational product(s) in human subjects. [Ref: Note for Guidance on Good Clinical Practice (CPMP/ICH/135/95): Annotated with TGA comments].

Low risk research is research where the only foreseeable risk to the participant 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. [Ref: National Statement on Ethical Conduct in Human Research (2007) incorporating all updates].

National Statement is the National Statement on Ethical Conduct in Human Research (2007) incorporating all updates [National Statement].

Negligible risk research is research where there is no foreseeable risk of harm or discomfort and any foreseeable risk is not more than inconvenience to the participants. Inconvenience is 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 survey or giving up time to participate in a research activity. Where the risk, even if unlikely, is more than inconvenience, the research is not negligible risk. [Ref: National Statement on Ethical Conduct in Human Research (2007) incorporating all updates].

Population health research is research directed towards preventing disease, prolonging life, and promoting health through the organised efforts of society.

Chief Investigator is the individual who takes responsibility for the overall conduct, management, monitoring and reporting of research including the submission of the project for ethical and scientific review. They are responsible for ongoing communication with the HREC.

Research is original investigation undertaken to gain knowledge, understanding and insight as described in the Australian Code for the Responsible Conduct for Research (2007).

Research protocol is a document that details the objectives, design, methodology, statistical considerations and organisation of a research project.

Serious adverse event (SAE):

For medicines also referred to as serious adverse drug reaction, is any untoward medical occurrence that at any dose:

- results in death;
- is life-threatening;
- requires in-patient hospitalisation or prolongation of existing hospitalisation;
- results in persistent or significant disability/incapacity;
- is a congenital anomaly/birth defect; or
- is a medically important event or reaction.

NOTE: The term 'life-threatening' in the definition of 'serious' refers to an event in which the patient was at risk of death at the time of the event; it does not refer to an event/reaction, which hypothetically might have caused death if it were more severe.

For devices is any adverse medical occurrence that:

- led to a death;
- led to a serious deterioration in health of a patient user or other.

This would include:

- a life threatening illness or injury;
- a permanent impairment of body function or permanent damage to a body structure;
 - a condition requiring hospitalisation or increased length of existing hospitalisation;
- a condition requiring unnecessary medical or surgical intervention; or
- foetal distress, foetal death or a congenital abnormality/birth defect;
- might have led to death or a serious deterioration in health had suitable action or intervention not taken place. This includes:
 - a malfunction of a device such that it has to be modified or temporarily/permanently taken out of service; or
 - a factor (deterioration in characteristics or performance) found on examination of the device. [Ref: Access to unapproved therapeutic goods via the Special Access Scheme (2009)].

Serious unexpected suspected adverse reaction (SUSAR) is a serious adverse event for which there is some degree of probability that the event is an adverse reaction to the administered drug, and the adverse reaction is unexpected.

Sponsor of a clinical trial is the company, institution or organisation, body or individual that takes overall responsibility for the conduct of the trial and usually initiates, organises and supports the clinical trial.

Therapeutic good is broadly defined as a good which is represented in any way to be, or is likely to be taken to be, for therapeutic use (unless specifically excluded or included under Section 7 of the Therapeutic Goods Act 1989). Therapeutic use means a product for use in humans in connection with:

- preventing, diagnosing, curing or alleviating a disease, ailment, defect or injury;
- influencing inhibiting or modifying a physiological process;
- testing the susceptibility of persons to a disease or ailment;
- influencing, controlling or preventing conception;
- testing for pregnancy; which includes things that are:
- used as an ingredient or component in the manufacture of therapeutic goods; or
- replacement or modification of parts of the anatomy. [Ref: <http://www.tga.gov.au/consumers/information-what-are-therapeutic-goods.htm>, last accessed 25/6/2013].

HREC 001: HRECs

Objectives

1.1. The objectives of the HRECs are to:

- a) Protect the mental and physical welfare, rights, dignity and safety of participants of research;
- b) Promote ethical principles in human research;
- c) Review research in accordance with the National Statement on Ethical Conduct in Human Research (2007) incorporating all updates [National Statement]; and
- d) Facilitate ethical research through efficient and effective review processes.

Functions

1.2. The HRECs function on behalf of the University of Queensland are to:

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

Accountability

1.3. The HRECs are directly accountable to the Deputy Vice- Chancellor (Research). The minutes of each HREC meeting are forwarded to the Deputy Vice Chancellor (Research) following confirmation.

1.4. The HRECs provide an annual report to the Deputy Vice- Chancellor (Research) at the end of calendar year.

1.5. The HRECs bring to the attention of the Deputy Vice- Chancellor (Research) issues of significant concern.

1.6. The HRECs provide the following reports on behalf of the University of Queensland:

- a) Australian Health Ethics Committee (AHEC) report in accordance with the requirements of the National Health and Medical Research Council (NHMRC), and any other reports as required.

1.7. Monitoring Measures: The HRECs will undertake their reviews in a timely and efficient manner and have mechanisms to monitor and evaluate their performance.

Communicating with Researchers

1.8 The Human Ethics Unit at UQ has an open door policy where researchers can stop by the Research Management Office to speak with a Human Ethics Coordinator or Operations Manager regarding questions they have with applications or UQ HREC procedures and processes.

1.9 The contact telephone numbers for the Human Ethics Unit are widely available on all HREC resources and on the web site for verbal contact.

1.10. The Chairpersons and HREC Coordinators will take into consideration the best method to use (writing, telephone, in person) for the issue at hand.

Scope of responsibility

1.11. The HRECs provide ethical and scientific review of research at sites within their jurisdiction.

1.12. The HRECs review human research applications for external institutions/organisations and investigators as approved by the Deputy Vice-Chancellor (Research).

Role of the Chairpersons

1.13. The Chairpersons are responsible for the conduct of HRECs' business and for ensuring that the HRECs reach decisions on all matters. Where the Chairpersons are unavailable the meeting will be chaired by the Deputy Chairperson if available, or by the alternate Deputy Chairperson if not. The Deputy Chairperson will be identified by the Chairperson. An alternative Deputy Chairperson will be identified by the committee members through election at the start of the meeting (as first item of business).

HREC Executive Committee

1.14. Each HREC has an Executive Committee comprising at least the HREC Chairperson or their delegate and a member of the ethics office (Ethics Coordinator).

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

- a) Ratification of approvals from other HRECs
- b) Low and negligible risk research applications;
- c) Amendments to current HREC approved projects;
- d) Responses to HREC queries, as approved by the full HREC for HREC Executive Committee review and approval;
- e) Annual progress reports and final reports; and
- f) Serious adverse events and suspected unexpected serious adverse reactions reports.

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

1.17. The Chairperson has the discretion to delegate to the Ethics Coordinator the authority to undertake review of HREC Executive Committee business that is considered administrative or within the capacity of the Ethics Coordinator such as:

- a) Amendments to Participant Information Sheets and Consent Forms that address changes requested by the HREC and require little interpretation of the ethical impact of the amendments. Changes include standard statements regarding insurance/indemnity, contact details, version control, or minor date changes.
- b) Amendments to other study documents (e.g. case report forms, patient diaries) that are administrative in nature or of low ethical risk;
- c) Changes to project personnel; and
- d) Other issues, on a case-by-case basis such as reviewing adherence to recommendation of the HREC with respect to minor changes, annual progress reports and final reports.

Information about HRECs

1.18. The University of Queensland notifies the NHMRC and determines the appropriate course of action, with the NHMRC and the monitoring of previously approved research.

HREC 002: HREC composition

2.1. The composition of the HRECs is in accordance with the National Statement. Minimum membership comprises eight members. As far as possible, men and women are represented in equal numbers and at least one-third of the members are external to the institution for which the HREC is reviewing research. The membership comprises representatives from the following categories:

- a) A Chairperson with suitable experience whose other responsibilities will not impair the HREC capacity to carry out its obligations under the National Statement;
- b) At least two members who are lay people, one man and one woman, with no affiliation with the institution or organisation and not currently involved in medical, scientific, legal or academic work;
- c) At least one member with knowledge of, and current experience in, the professional care, counselling or treatment of people;
- d) At least one member who performs a pastoral care role in the community, for example, an Aboriginal elder or a minister of religion;
- e) At least one member who is a lawyer, where possible one who is not engaged to advise the institution for which the HREC is reviewing research; and
- f) At least two members with knowledge of and current research experience that is relevant to the applications to be considered at the meetings they attend.

2.2. To ensure the HREC is equipped to address all of the relevant considerations arising from the categories of research, some or all of the above membership categories may be represented by more than one person.

2.3. No member is appointed in more than one of the membership categories. The University of Queensland aims to establish a pool of inducted members in each category who attend meetings as needed to meet the HREC requirements and are available to provide expertise for the research under review.

2.4. The HRECs are free to consult person(s) considered by the HRECs to be qualified to advise and assist in reviewing applications provided that there is no conflict of interest and an undertaking of confidentiality is given. Such person(s) are not entitled to vote on any matter.

HREC 003: Appointment of members

3.1. HREC members are recruited by direct approach, nomination or by advertisement through an open and transparent process.

3.2. Prospective members may be invited to observe a meeting of the HREC.

3.3. Prospective members are asked to provide a copy of their curriculum vitae to a selection committee comprising the Chairperson, Ethics Coordinator and at least one other HREC member. The selection committee interviews prospective members, consults with HREC members and makes a recommendation on new appointments to the Deputy Vice Chancellor (Research).

3.4. Members are appointed as individuals for their knowledge, qualities and experience and not as representatives of any organisation, group or opinion.

3.5. Membership of the HRECs are made publicly available.

3.6. All members including the Chairpersons and Deputy Chairpersons are appointed by the Deputy Vice Chancellor (Research). The letter of appointment includes the date of appointment, length of tenure, indemnity and termination.

3.7. Eligible members (such as lay members or non-affiliated members) of the HREC will be offered an honorarium for attending each committee meeting. The value of the honorarium will be determined by institutional policy. Upon appointment, members are provided with an orientation package and asked to sign a statement undertaking:

a) that all matters of which he/she becomes aware during the course of his/her work on the HREC will be kept confidential;

b) that any conflicts of interest, which exist or may arise during his/her tenure on the HREC will be declared both annually via reporting at the first meeting each year, and verbally at the commencement of each meeting should a specific CoI regarding an application arise; and

c) that he/she has not been subject to any criminal conviction or disciplinary action, which may prejudice his/her standing as an HREC member.

3.9. Members are appointed for a period of up to 3 years and may serve a total of 6 years (two consecutive terms) unless otherwise approved by the Deputy Vice Chancellor (Research). The Deputy Vice- Chancellor (Research), in consultation with the Chairperson, may implement a probationary period.

3.10. The Chairperson and Deputy Chairperson may serve longer terms with the approval of the Deputy Vice-Chancellor (Research). Members are advised when their term is due to expire. Reappointment is by application to the Chairperson of the relevant HREC who then makes a recommendation to the Deputy Vice Chancellor (Research).

3.11. The University of Queensland will review membership at least every three years. New and renewed appointments allow for continuity, development of expertise within the HRECs, and regular input of fresh ideas and approaches.

3.12. All members sign a conflict of interest declaration at commencement and then annual thereafter. The declaration will be maintained on the members personnel file.

3.13. Membership lapses if a member fails to attend:

a) Three consecutive meetings without reasonable excuse/apology or exceptional circumstances; and

b) At least two thirds of all scheduled HREC meetings in each year, barring exceptional circumstances.

3.14. The Chairperson notifies the member of a lapse of membership in writing. Steps are taken to fill the vacancy.

3.15. Members seeking to resign or take a leave of absence for an extended period from the HREC are asked to give notice to the Chairperson. Steps are taken to fill the vacancy.

3.16. The appointment of any member of the HREC may be terminated if the Deputy Vice Chancellor (Research) is of the opinion that:

- a) It is necessary for the proper and effective functioning of the HRECs;
- b) The person is not a fit and proper person to serve on an HREC; or
- c) The person has failed to carry out their duties as an HREC member.

Committee members may not appeal their termination and there are no dispute resolution options available to terminated committee members.

3.17. Members are expected to participate in relevant specialised working groups as required.

3.18. The Chairperson is expected to be available between meetings to participate in HREC Executive Committee meetings where required.

3.19. The University of Queensland provides indemnity for members of the HREC for liabilities that arise as a result of the member exercising their duties in good faith.

HREC 004: Orientation and training of members

4.1. New HREC members are provided with orientation/training as determined to be appropriate by the University of Queensland.

4.2. Orientation involves some or all of the following:

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

4.3. Each member is:

- a) expected to become familiar with the National Statement and consult other guidelines relevant to the review of specific research applications;
 - b) encouraged to attend continuing education or professional development activities in research ethics on an annual basis and, at a minimum, at least once in each period of appointment.
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HREC 005: Meeting schedules

5.1. The HRECs meet on a regular basis at least every month – the exception being in Dec/Jan, when a decision will be made by the Chairs and Ethics Coordinators as to when the meetings for these months will be held. The HREC holds at least 11 scheduled meetings in each year for the purpose of reviewing new applications.

5.2. Meeting dates and application closing dates are made publicly available on UQ's web site.

5.3. Additional meetings are held where necessary to ensure that reviews are completed within a timely fashion, to discuss matters relating to the establishment or operating procedures of the HRECs or for training purposes.

5.4. The schedule of HREC meetings for the calendar year commencing 1 January is ratified by the HRECs before or at the last meeting of the previous year. The schedule sets out the dates, times and venues of meetings, and the closing date for submission of applications.

HREC 006: Agenda

- 6.1. The Ethics Coordinator prepares an agenda for each HREC meeting.
- 6.2. The meeting agenda and associated documents are circulated to HREC members at least 7 days prior to the next meeting electronically and/or as paper copies.
- 6.3. Documentation received after the closing date are included on the agenda and/or tabled at the meeting at the discretion of the Ethics Coordinator and/or Chairperson.
- 6.4. New applications received after the closing date are not tabled at the meeting.
- 6.5. As a minimum, the agenda includes the following items:
 - a) Attendance and apologies;
 - b) Declarations of conflicts of interest relating to agenda items;
 - c) Confirmation of minutes of the previous HREC meeting;
 - d) Business arising since the previous meeting(s) that the HREC indicated it wished to reconsider;
 - e) Minutes of meetings and any issues for noting and/or approving from the HREC Executive Committee, subcommittees and external expert reviewers for example;
 - f) Amendments to documents or modifications to applications and research projects, unless previously approved by the Executive Committee;
 - g) Annual progress reports and final reports;
 - h) Reports of serious adverse events and suspected unexpected serious adverse reactions;
 - i) New applications for review and, if applicable, the spokesperson or lead reviewer nominated by the HREC to lead the discussion on each application;
 - j) General business; and
 - k) Notification of the date, time and venue of the next scheduled meeting.
- 6.6. The agenda and all documentation are confidential.

HREC 007: Lead reviewers

7.1. The HRECs have the discretion to appoint one or more members as lead reviewers for the HREC meetings for each application.

7.2. Allocation of applications to lead reviewers is made by the Ethics Coordinators in consultation with the Chairpersons, as necessary.

7.3. The lead reviewer is provided with a copy of the application and other supporting documentation which they have been allocated to review.

7.4. The specific role undertaken by the lead reviewer both at the meeting and following the meeting is at the discretion of the HREC. Local procedures are discussed and agreed by the members.

HREC 008: Submission of New Applications

8.1. In accordance with UQ Policy, all human research that takes place in UQ or by a student or staff member of UQ must be reviewed and approved in accordance with the National Statement.

8.2. All applications for ethical and scientific review will be submitted to the HREC Ethics Coordinator by the Chief Investigator using any of the following forms:

- a) NHMRC Human Research Ethics Application (HREA)
- b) NHMRC National Ethics Application Form (NEAF)
- c) UQ Ethics Application Form

8.3. The HREA form will be completed on its web site (hrea.gov.au); the NEAF form will be completed on its web site (neaf.gov.au), and the UQ application form is available on the UQ web site.

8.4. Each Website provides guidance on how to complete the respective forms.

8.5. Applications for full HREC review will be submitted to the Ethics Coordinator of the HREC by the published closing date.

8.6. The closing dates for applications for full HREC review will be no longer than 10 working days prior to each HREC meeting.

8.7. The application and supporting documentation must be emailed to ethics@uq.edu.au by 2.00pm on the closing date. Applications received after this time will be kept for the following meeting.

8.8. Electronic signatures on the application form are acceptable.

HREC 009: Full HREC Review

9.1. In accordance with the National Statement, the following types of human research will be ethically and scientifically reviewed and approved by a full HREC before they take place in UQ or by UQ students and/or staff.

a) Research that involves more than low risk to participants.

b) Research that includes any of the following:

Interventions and therapies, including clinical and non-clinical trials and innovations or new treatment modalities;

Active concealment or planned deception of participants;

Exposure of illegal activities; and

Research specifically targeting Aboriginal or Torres Strait Islander peoples.

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; and

People who may be involved in illegal activities.

9.2. All applications for full HREC review by a UQ HREC will be made by the Chief Investigator using the Human Research Ethics Application (HREA), the National Ethics Application Form (NEAF), or UQ Ethics Application Form completed via their respective Websites.

Allocation of applications

9.3. The Ethics Coordinator will determine, in consultation with the HREC Chairperson if required, the review requirements of an application prior to full review by the HREC (e.g. lead reviewer or external expert reviewer).

9.4. The HREC will, at its discretion, cap the number of applications it reviews at each meeting to ensure the rigour of its review process.

9.5 To ensure the timely review of applications, the meeting schedule for UQ's two registered HRECs is set for alternating fortnightly meetings.

Validation of applications

9.6. The Ethics Coordinator will determine whether the application is valid and send an acknowledgement to the Chief Investigator, generally within 5 working days of receiving the application, by email. If required, the Ethics Coordinator will contact the Chief Investigator by telephone or email to request that they provide any missing information before issuing a formal acknowledgement. The acknowledgement will include details of dates of the meeting(s) at which the application will be discussed and the HREC Reference Number.

9.7. An application will be accepted if it meets the following criteria:

a) Documents relevant to the particular application are submitted in accordance with the HREC requirements;

b) All sections and questions on the application form are completed;

c) The application has been signed by the Chief Investigator, all listed co-investigators and their Head of School;

d) Supporting documents are marked with version numbers and dates in the case of the research protocol, Participant Information Sheet and Consent Forms, letters to participants or others with an interest in the research, diaries, identification cards and any other documentation to be used in the research that is not already scientifically validated and referenced;

e) All relevant scientific and technical assessments and reports (e.g. radiation, drug and biosafety committee reports) are included.

Invalid applications

9.8. Where an application is not submitted on the correct application form and/or is missing the required supporting documents or significant sections of the form is incomplete, the Chief Investigator will be notified by email explaining that the application will not be accepted for the current meeting and that further documentation/completion of the correct form is required prior to HREC review.

HREC 010: Attendance of the Chief Investigator

10.1. At the request of the HREC Chairperson, the Chief Investigator may be invited to make a formal presentation or to respond directly to requests from the HREC for further information, clarification or reassurance.

10.2. Where the Chief Investigator is unable to attend, another key investigator or collaborator is invited to attend, if appropriate. Representatives of the sponsor are not to attend the meeting in place of the Chief Investigator. At the discretion of the HREC Chairperson additional members of the research team may attend with the Chief Investigator.

10.3. The Chief Investigator attends the meeting in person or via telephone or videoconference.

HREC 011: Quorum requirements

11.1. A quorum is required at each meeting for the HREC to reach a final decision on any agenda item. The quorum for meetings is at least one member from each category, and two members from category (f), as specified in the National Statement attending in person or via telephone or videoconference.

11.2. A meeting can proceed where there is less than a full attendance of the minimum membership at a meeting but only if the Chairperson is satisfied “that the views of those absent who belong to the minimum membership have been received and considered”, for instance through prior submission of written comments.

11.3. Where a quorum is not reached, the HREC will not commence, continue or conclude discussion with the purpose of reviewing an application. The HREC has the discretion to proceed with other business on the agenda as if it were an HREC Executive Committee meeting, provided that the Chairperson (or Deputy Chairperson or alternate Deputy Chairperson) and at least one other member is present.

11.4. Where the Ethics Coordinator of an HREC is concerned that a forthcoming meeting will not be attended by a quorum of members the Ethics Coordinator notifies the Chairperson and the following options are considered:

- a) Postponing and re-arranging the meeting; or
- b) Cancelling the meeting.

HREC 012: External expert reviewers: Use of external expert reviewers

12.1. An HREC unable to make a decision on an application or without the necessary expertise is able to consult experts identified in the area by the Chairperson and/or the Ethics Coordinator.

12.2. Advice from other external expert reviewers is sought through the following procedures

- a) Notification is sent to the Chief Investigator either before or following the HREC meeting explaining that a final decision will not be made on the application until advice is obtained from an expert reviewer. The letter notifies the Chief Investigator of the issues of concern to the HREC, but does not request further information or clarification. In circumstances where expert scientific opinion is sought, the Chief Investigator is given the option to identify experts to whom they object.
- b) A suitable expert reviewer is identified by the Chairperson/Ethics Coordinator or by the HREC during the meeting.
- c) The Chairperson or Ethics Coordinator initially contacts the prospective expert reviewer(s) by telephone or email to establish whether they are available to provide expert advice within the required time frame and that they have no connection with the research that might give rise to a conflict of interest. The expert reviewer is advised about confidentiality requirements.
- d) The Ethics Coordinator specifies in writing the issues of concern to the HREC and the expert advice required, and requests written advice and/or attendance (but not voting) at the HREC meeting. The Ethics Coordinator ensures that the expert reviewer declares any conflict of interest and signs a declaration and confidentiality agreement.

12.3. A copy of the application form is provided together with any supporting documentation required by the expert reviewer. The HREC, or HREC Executive Committee as appropriate, considers the advice of the expert reviewer and makes an independent decision on the ethical and scientific acceptability of the application. The advice is recorded in the minutes.

HREC 013: Declaration of interest

13.1. An HREC member declares to the HREC any conflicts of interest they have in relation to an application for ethical and scientific review or any other matter for consideration at that meeting. Conflict of interest includes financial interests, personal, professional or institutional benefits or advantages that depend significantly on the research outcomes.

13.2. Declarations are made orally at the meeting prior to the matter being considered or in writing to the Chairperson prior to the meeting. The HREC determines whether the level of interest results in:

a) A substantial conflict of interest: a member is excluded from the meeting where there is a substantial conflict of interest until the HREC has concluded consideration of the matter. Being an investigator on a research project is considered to represent a substantial conflict of interest.

b) A non-substantial conflict of interest: the member has the discretion to leave during the discussion of the matter.

13.3. The minutes record declaration of interest and the decision of the HREC on the procedures to be followed.

HREC 014: Confidentiality

Confidentiality of meetings

14.1. The confidentiality of HREC proceedings is essential as:

- a) Members do not sit on the HREC in a representative capacity;
- b) Applications need to be discussed freely; and
- c) Applications may have commercial implications.

14.2. HREC meetings are held in private and members are encouraged to raise matters of concern.

14.3. Confidentiality is addressed in two ways:

- a) The HREC Terms of Reference; and
- b) Members signing a statement of undertaking upon appointment.

14.4. Attendance of visitors or observers at a meeting, as appropriate and approved by the Chairperson, is conditional on the attendee signing a confidentiality agreement.

Confidentiality of applications

14.5. Applications supporting documentation and correspondence are treated confidentially.

14.6. External expert reviewers providing advice to the HREC are asked to sign a confidentiality agreement.

14.7. HREC correspondence is addressed to the Chief Investigator and sent to the Chief Investigator or the relevant contact person identified on the application form. Correspondence is not released to the sponsor or any other parties.

14.8. Chief Investigators forward information about matters raised in the ethical review to sponsors or other parties where necessary.

HREC 015: Decision making

15.1. Members present are allowed reasonable opportunity to express relevant views on matters on the agenda.

15.2. The HREC endeavours to reach a decision concerning the ethical and scientific acceptability of a research project by unanimous agreement.

15.3. Where a unanimous decision is not reached, the Chair will need to facilitate the expression of opinion from all members, identify points of agreement and of disagreements and judge when a sufficient degree of general agreement has been reached.

15.4. Any significant minority view (i.e. 2 or more members) is noted in the minutes.

15.5. Discussions of significant issues and decisions are recorded in the minutes. Where members wish, a record of their formal dissent from the decision of the HREC is recorded in the minutes.

15.6. To encourage free and open discussion and to emphasise the collegiate character of the HREC, particular views are not attributed to particular individuals in the minutes, except in circumstances where a member seeks to have their opinions or objections recorded.

15.7. An HREC member unable to attend a meeting may submit comments in writing on agenda items to the Ethics Coordinator or Chairperson prior to the meeting. Submission of written comments is recorded in the minutes.

HREC 016: Decisions available to the HREC

16.1. The HRECs select one of the following decisions on any application reviewed at a meeting and the decision is recorded in the minutes:

- a) Approve the application as being ethically and scientifically acceptable;
- b) Request modification or further information/clarification;
- c) Seek further advice from external expert reviewer(s); or
- d) Reject the application.

16.2. The Chairperson ensures that one of the above decisions is made on every application considered at an HREC meeting.

16.3. Where the HREC decides that further information or clarification is required, the Chairperson ensures that:

- a) Further information or clarification required is specifically identified at the meeting; and
- b) Delegation of responsibility for considering the further information or clarification and confirming the final HREC opinion is clearly agreed, i.e. the information will need to be re-submitted to the full HREC, a number of HREC members or the HREC Executive Committee.

HREC 017: Notification of HREC Decisions

17.1. The procedures outlined in this section apply to notification of the outcome of full and expedited HREC review.

17.2. Following confirmation of the minutes by the Chairperson, the Human Ethics Coordinator will notify the Chief Investigator of the decision in writing within 10 working days of the meeting.

Requests for modification/further information

17.3. The following information will be included in the letter of notification:

- a) The decision reached by the HREC or HREC Executive Committee;
- b) Requests for modification of or further information for the research project with reference to the National Statement or relevant legislation where necessary and the process for approval of the modifications as agreed by the HREC or HREC Executive Committee; and
- c) Notification that a response be provided within 3 months or two HREC meetings (whichever occurs sooner). After this time the application is considered withdrawn and the Chief Investigator will be required to submit a new application.

Approved research projects

17.4. Final approval for a research project will be given at:

- a) the full HREC meeting where the application was initially considered; or
- b) the full HREC meeting where the response to a request for modification/ further information was considered; or
- c) the HREC Executive Committee meeting where the low and negligible risk application was initially considered; or
- d) the HREC Executive Committee meeting where the response to a request for modification/further information was considered.

17.5. The following information will be included in the approval letter:

- a) The decision reached by the HREC or HREC Executive Committee;
- b) A list of all approved documents including version numbers and dates;
- c) Duration of ethical and scientific approval; and
- d) Confirmation that the HREC composition is in accordance with the National Statement;

17.6. Additional approval conditions specified by the HREC or HREC Executive Committee for a particular application, for example a requirement for more frequent progress reports, will be included in the approval letter.

17.7. Approved projects will be expected to commence within 12 months of the date on which a favourable ethical and scientific decision is given by the HREC. A project commences when any study procedure or any part of the protocol is implemented.

17.9. Where the project does not commence within 12 months, the Chief Investigator will provide the HREC with an explanation in the annual progress report.

Rejected research projects

17.10. Where the research project is rejected, the following information will be included in the letter of notification:

- a) The decision of the HREC or HREC Executive Committee;
- b) Full explanation of reasons by reference to the National Statement or relevant legislation where necessary; and
- c) Advice regarding available options for further review.

HREC 018: Minutes

18.1. The Ethics Coordinator prepares the minutes of the HREC meeting in consultation with the Chairperson and other members as necessary. The minutes are subsequently approved by the Chairperson within 10 working days of the meeting.

18.2. The minutes reflect each item listed for discussion on the agenda:

- a) Attendance and apologies;
- b) Declarations of conflicts of interest relating to agenda items;
- c) Confirmation of minutes of the previous HREC meeting;
- d) Business arising since the previous meeting(s) that the HREC indicated it wished to reconsider;
- e) Minutes of meetings and any issues for noting and/or approving from the HREC Executive Committee, subcommittees and external expert reviewers;
- f) Amendments to documents or modifications to applications and research projects;
- g) Annual progress reports and final reports; and
- h) Reports of serious adverse events and suspected unexpected serious adverse reactions.
- i) HREC deliberations and decisions on new applications, whether in the main text of the minutes or in attachments:
 - Submission of written comments by members;
 - Summaries of the advice given by expert or lead reviewers;
 - Summaries of the main issues considered;
 - Decisions of the HREC on the application; and
 - Formal dissent from the decision of the HREC by a member and the reason for it and/or any significant minority views (i.e. 2 or more members)
- j) General business; and
- k) Notification of the date, time and venue of the next scheduled meeting.

18.3. The minutes are submitted at the next meeting of the HREC for ratification as a true and accurate record of the previous meeting. Members are given the opportunity to seek amendments to the minutes prior to their finalisation.

18.4. The minutes are confidential to the HREC and are not disclosed to investigators or sponsors.

15185. The minutes of HREC meetings are made available to the Deputy Vice-Chancellor (Research)

HREC 019: Duration of HREC approval

19.1.HREC approval applies for the duration requested, up to a maximum of five years, subject to annual reporting as required by the National Statement.

19.2 The HRECs may, at their discretion, take action to suspend or terminate the decision.

19.3.The request to extend the duration of the research project is submitted by the Chief Investigator as an amendment for review by the HRECs in the first instance.

19.4.HREC approval for an extension applies for the duration requested, up to a maximum of five years, except where action is taken to suspend or terminate the decision.

HREC 020: Monitoring approved research projects

20.1. The HREC will monitor approved research projects to ensure compliance with the conditions of approval and to protect the rights, safety and welfare of participants. This includes review of annual progress reports and final reports, safety reports and reports of protocol violations.

20.2. The HREC has the discretion to adopt other appropriate mechanisms for monitoring depending on the complexity, design and risk perceived, including:

- a) Discussion of relevant aspects of the project with the investigators, at any time;
- b) Random inspections of research sites, data, or consent documentation;
- c) Interviews with research participants or other forms of feedback from them; and
- d) Request and review reports from independent agencies such as a Data and Safety Monitoring Board.

20.3. The HREC will, at its discretion, recommend in the letter of approval that the site coordinates on-site monitoring at recommended intervals or randomly throughout the project.

Annual progress reports

20.4. Annual progress reports will be submitted to the reviewing HREC by the Chief Investigator. The first report will be submitted 12 months from the date of ethical approval.

20.5. The Executive Officer will send a reminder email where a report is not received by the due date. If there is no response after 30 calendar days, a second reminder email will be sent requesting the Chief Investigator to contact the Chairperson to discuss the report. If the report is still not received after a further period of 30 calendar days, the Chairperson will consider further action. Where suspension of HREC approval is proposed, the matter will be considered at a full HREC meeting.

20.6. Annual progress reports will be added to the agenda and reviewed by the HREC Executive Committee. The HREC will inform the Chief Investigator of the outcome of the review within 10 working days of the meeting, unless immediate notification is required.

20.7. The HREC will have the discretion to request more frequent progress reports, depending on the complexity, design and risk perceived.

Final reports

20.8. Final reports will be submitted to the reviewing HREC by the Chief Investigator, upon completion of the research project. Final reports will include a copy of the final results and publications if available. If project data and interpretation are fully addressed in a publication, a separate copy of final results will not be required.

20.9. Final reports will be added to the agenda and reviewed by the HREC Executive Committee. The HREC file will be archived as an electronic and/or hard copy, according to the UQ archiving policy, once the final report is acknowledged.

Protocol deviation/violation reports

20.10. Protocol deviations are minor or administrative departures from HREC approved protocol procedures whereby data is unusable or not available, but which do not affect the scientific soundness of the research plan or the rights, safety, or welfare of research participants. Examples include: follow up visits that occurred outside the protocol required time frame because of the participant's schedule, or blood samples obtained at times close to but not precisely at the time points specified in the protocol.

20.11. The Chief Investigator will provide a list of protocol deviations with the annual progress report.

20.12. Protocol violations are instances where the protocol requirements and/or regulatory guidelines were not followed, and are generally more serious in nature than protocol deviations. Protocol violations are considered to potentially affect the scientific soundness of

the research plan and/or the rights, safety, or welfare of research participants. Examples include: failure to obtain participant consent and participant inclusion/exclusion violations.

20.13. The Chief Investigators will provide to the HREC written reports of protocol violations in a timely manner.

HREC 021: Urgent safety-related measures

21.1. Where it is necessary to eliminate an immediate hazard to the research participants, modifications or changes to the research project will be implemented without prior HREC review.

21.2. The Chief Investigator will notify the HREC of amendments arising from urgent safety-related events immediately and in writing (email is acceptable). The Chief Investigator will submit the implemented modification or change, the reasons for it, and, if appropriate, the proposed protocol amendment(s) to the HREC for review within 5 working days.

21.3. Review of amendments from urgent safety-related events will be expedited by the HREC Executive Committee.

21.4. Reports of urgent safety-related measures are in addition to adverse event reporting requirements.

HREC 022: Adverse Event Reporting

Clinical trials involving therapeutic products

22.1. For clinical trials involving therapeutic products, adverse event reporting will meet the requirements of the National Health and Medical Research Council, Australian Health Ethics Committee (AHEC) Position Statement “Monitoring and reporting of safety for clinical trials involving therapeutic products” (May 2009), which can be found at:

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

22.2. Table 1, adapted from the AHEC Position Statement, summarises the requirements for safety reporting to the UQ HREC for clinical trials involving therapeutic products.

22.3. The Chief Investigator will report serious adverse events (SAEs) and suspected unexpected serious adverse reactions (SUSARs), occurring at the site directly to the reviewing HREC.

22.4 Depending on the complexity, design and risk perceived, the UQ HREC has the discretion to require that additional information be reported.

Table 1: Safety reporting to the reviewing HREC: for clinical trials involving therapeutic products.

Frequency	Items to be reported to HREC
In a prompt manner	<ul style="list-style-type: none"> • Serious adverse events (SAEs) and suspected unexpected serious adverse reactions (SUSARs), with comment from the Chief Investigator. • Reporting within 72 hours of the event occurring, unless the Chief Investigator considers immediate notification is required. • Where there is only a local Data and Safety Monitoring Board for the project (e.g. investigator initiated trial), notification within 24 hours of the event occurring. • Information, which materially impacts the continued ethical acceptability of the trial. • Information that requires, or indicates the need for, a change to the trial protocol, including changed safety monitoring in the view of the Chief Investigator or sponsor.
At least every 6-monthly	<ul style="list-style-type: none"> • Listing of all suspected unexpected serious adverse reactions, Australian and international, occurring with a compound or device including sponsor and Chief Investigator comment as to whether action is planned for the trial on the basis of the reports. (European Union format is acceptable.)
At least annually	<ul style="list-style-type: none"> • An updated Investigator Brochure (IB), or • A European Union Annual Safety Report (EU ASR) or similar format report, or • Current, approved product information (PI), if appropriate (e.g. in a study for a product approved in Australia or where an Investigator Brochure is no longer maintained). • Include sponsor and Chief Investigator comment as to whether action is planned for the trial on the basis of the report. • For trials that are investigator or collaborative group sponsored in which an IB, EU ASR or PI is not available, then a trial update may be submitted that provides appropriate review of safety information in the previous 12 months • Include Chief Investigator's own opinion in regard to potential impact on ethical acceptability and need for action. • Other reports consistent with section 5.5.5 of the National Statement and Good Clinical Practice adopted by the Therapeutic Goods Administration.

Review of safety reports by the HREC

22.5. Safety reports will be reviewed by the HREC Executive Committee to determine the appropriate course of action.

22.6. If the HREC Executive Committee deems further information is required it will request this from: a) an independent expert with expertise in the area;
or b) the Chief Investigator who submitted the report.

22.7. For reported deaths the HREC will, at its discretion, request information such as autopsy reports and terminal medical records.

22.8. Following review, the HREC will take the appropriate course of action which will include, but not be limited to one or more of the following:

- a) Including a notation on file of the safety-related occurrence;
- b) Increasing monitoring of the research project;
- c) Requesting an amendment to the project and/or Participant Information Sheet and Consent Form and any other study documents;
- d) Suspending ethical approval; and
- e) Withdrawing ethical approval.

Notification of HREC review outcome

22.9. The HREC will inform the Chief Investigator of the outcome of the review within 10 working days of the meeting, unless immediate notification is required for urgent safety reasons.

HREC 023: HREC reporting requirements

23.1. The ratified minutes of each HREC meeting are forwarded to the Deputy Vice Chancellor (Research).

23.2. The HREC provides an annual report to the Deputy Vice- Chancellor (Research), which includes:

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

23.3. The HREC completes and submits reports on behalf of the University of Queensland to the Australian Health Ethics Committee (AHEC) in accordance with the requirements of the NHMRC; and any other reports as required.

23.4 In the event an ethics approval is suspended or withdrawn (per 17.2(f) above), the HREC will immediately notify any other HRECs mentioned in the application of that withdrawal, detailing the reason for suspension or withdrawal of approval.

HREC 024: Clinical Trial Notification and Clinical Trial Exemption schemes

24.1. Unapproved therapeutic goods have undergone limited or no evaluation of quality, safety or efficacy by the Therapeutic Goods Administration (TGA). Use of these products is considered to be experimental and potentially carries risks that have not been defined in the Australian context.

24.2. There are two schemes under which clinical trials involving a new therapeutic good or new uses of a therapeutic good can be conducted in Australia: the Clinical Trial Notification (CTN) scheme and the Clinical Trial Exemption (CTX) scheme.

24.3. The investigator's obligations under the Therapeutic Goods Act 1989 and application forms to conduct clinical trials under the CTN or CTX scheme are detailed at: <http://www.tga.gov.au/industry/clinical-trials-guidelines.htm> CTN/CTX HREC application requirements

24.4. The investigator completes all sections of the CTN or CTX form before submission to the HREC, including details of:

- a) Investigational product;
- b) Comparator product (if applicable);
- c) All other drugs administered as part of the trial (approved and unapproved);
- d) Trial site;
- e) Sponsor; and
- f) Investigator.

24.5. For review of a trial under the CTX scheme, the investigator also provides the HREC with all related correspondence to and from the TGA.

24.6. The CTN or CTX form, signed by the Chief Investigator, is provided to the HREC at the time of submission of a new application.

24.7. If the application is approved, the HREC signs the CTN or CTX form at section 3 and returns it to the Chief Investigator.

HREC 025: Suspension or withdrawal of HREC approval

25.1. The HREC will suspend ethical and scientific approval if satisfied that a research project is not, or cannot be, conducted in accordance with the approval or that the rights, safety or welfare of participants may be compromised. Suspension can relate to some or all project activities. Certain aspects of the protocol will continue to ensure participant safety even if a project is suspended, for example; collection of safety data, administration of study drug or study procedures that are not related to the grounds for suspension. At a minimum suspension will involve cessation of participant recruitment. The HREC will specify what aspects of the project will cease and when activities can recommence.

25.2. Where the HREC suspends ethical approval, the Chief Investigator will be notified in writing within 3 working days of the decision to suspend, unless immediate notification is required for urgent safety reasons.

25.3. Upon suspension, the HREC Chairperson with the support of the Ethics Coordinator and other nominated members of the HREC will investigate the conduct of the project and compile a report for consideration by the full HREC and the Chief investigator.

25.4. The Chief Investigator will be requested to respond to the report.

25.5. The full HREC will consider the response of the Chief Investigator to the report and decide on the conditions for reinstatement of approval or whether approval will be withdrawn.

25.6. The HREC will notify the Chief Investigator of its decision.

25.7. An investigator will discontinue research following suspension or withdrawal of ethical and scientific approval and will comply with the special conditions imposed by the HREC.

25.8 As required by the National Statement, any other HRECs involved in the project will be notified of the suspension or withdrawal of HREC approval.

HREC 026: Complaints

Complaints about the conduct of an approved research project

Complaints about the conduct of an authorised research project will be reported to the nominated contact of the reviewing HREC (e.g. Ethics Coordinator). The complainant will receive an acknowledgement in writing where possible.

UQ will investigate the complaint and conduct an audit of the project if necessary. Where the complaint relates to suspected research misconduct, the matter will be dealt with in accordance with the Australian Code for the Responsible Conduct for Research (2007) by the National Health and Medical Research Council, Australian Research Council, and Universities Australia and UQ Policies PPL 4.20.02 (Responsible Conduct of Research) and PPL 4.20.05 (Research Misconduct) as well as any other relevant Human Resources or Research policies.

UQ will inform the following parties of the final outcome of any investigation/audit:

- a) the complainant; and
- b) the Chief Investigator and/or other investigators to whom the complaint relates;

Complaints about the conduct of HREC members

Complaints about the conduct of an HREC member will be managed using the following process:

- a) A complaint will be submitted in writing to the Deputy Vice Chancellor Research. The Deputy Vice-Chancellor (Research) (or delegate) will inform the Chairperson of the complaint received. The Deputy Vice-Chancellor (Research) (or delegate) will acknowledge the complaint in writing.
- b) The Deputy Vice-Chancellor, Research (or delegate) will investigate the complaint by establishing a panel.
- c) The panel will include the following members: The Deputy Vice-Chancellor, Research or their nominee as convenor; and Two nominees of the Deputy Vice-Chancellor, Research (not members of the same HREC).
- d) The panel will afford the subject HREC member and the complainant the opportunity to make submissions.
- e) The Deputy Vice-Chancellor, Research (or delegate) will notify the subject HREC member and the complainant of the outcome of the investigation. The possible outcomes include:
 - The complaint is dismissed; or
 - The complaint upheld and the panel make recommendation to resolve the issues based on the findings of the panel.