General Guidelines

Purpose:

It is the responsibility of the Uniting*Care* Health Human Research Ethics Committee to safeguard the rights, safety and well being of all human subjects enrolled in research conducted within its facilities. To this end, research involving human subjects is reviewed to ensure it is scientifically valid and ethically acceptable and that it will conform to the ethical guidelines as outlined in the National Statement on Ethical Conduct of Research involving Humans.

What Needs Review?

All human subject research conducted by medical and other staff and involving patients, staff, resources or data in Uniting*Care* Health facilities is to be reviewed and approved before the research begins. The Committee shall also review research involving human remains, cadavers, tissues, biological fluids, embryos or foetuses.

Research

Research is any systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.[1]
When an activity involving a patient is undertaken with the prime purpose of testing a hypothesis and permitting conclusions to be drawn with the intention of contributing to medical knowledge, it becomes research.[2]

Quality assurance studies are not normally required to undergo ethics review. Ethics review is required, however, if they contain an element of research.
The opinion of the Human Research Ethics Committee should be sought whenever there is any doubt about the applicability of committee review to any project.

The Human Research Ethics Committee:

Representation is structured according to the requirements of the National Health and Medical Research Council (NH&MRC) as set out in the *National Statement on Ethical Conduct of Research involving Humans*. The committee meets on a two monthly basis.

Closing date for applications:

The closing dates for application submission for Uniting*Care* Health HREC are listed on the Initial Application Submission Notes document and on our website.

For research projects that require funding approval before the project can commence it is recommended that an application for ethics approval be submitted once the funding is obtained. Significant delays in start-up or changes to the protocol due to funding agency requirements may require a new submission to the HREC.

[1] National Institute of Health Primer: Research and Privacy
[2] MRC South Africa: Guidelines on Ethics in Medical Research

Submission Requirements:

Submissions to the Human Research Ethics Committee must be complete, with all appropriate documentation appended. All required documentation has been identified on the Committee's application protocol which includes a submission checklist. Incomplete applications or applications not conforming to requirements will be returned for revision and re-submission. Submissions must be typed and copies should be legible.

The Human Research Ethics Committee reserves the right to defer any submission that is lacking information critical to the considerations of the Committee.

The following information and guidelines are intended to assist investigators in preparing their proposals for submission to the UHC Human Research Ethics Committee. For any questions, or to obtain a preliminary review of your submission materials, contact the Ethics office (Tel 07 3232 7500).

Applicable forms can be obtained from the Ethics office. Submissions must include:

1. Completed checklist
2. Completed submission form
3. Informed consent form(s).
4. Final research protocols.
5. Product monograph or Investigator's Brochure for studies involving investigational drugs/devices.
6. Copies of questionnaires or any measuring instruments to be used in the study.
7. Any advertisements for recruitment of study subjects (if applicable).
8. Results from any previous review. If this proposal has received previous scientific review, please attach copies of any reviews and funding/acceptance letter.
9. Format of Submissions:

The Guidelines are designed to assist investigators in preparing research proposals and consent forms for use in the Uniting*Care* Health facilities/services. It is recommended that investigators follow the format of the Guidelines for both the protocol and the consent forms. Review of the submission will be facilitated by the use of the suggested formats.

Submission Categories:

Submissions to the Board will be classified as either:

- Category A or
- Category B

Category A submissions will require presentation to the full committee.

Category B submissions are sent to one or more members of the HREC for review and are not presented to the full committee for approval. Categories of research that may be given category B review include:

1. Studies involving "minimal risk" [3]
2. Extensions or amendments of previously-approved proposals or consent forms with the proposed changes presenting minimal additional risk to patients
3. New studies that involve only minor modifications to a previously approved proposal.

[3] Minimal risk is defined as follows: if potential subjects can reasonably be expected to regard the probability and magnitude of possible harms implied by participation in the research to be no greater than those encountered by the subject in those aspects of his or her everyday life that relate to the research.

Other submissions that may be reviewed by the category B process using the appropriate form when applicable:

1. Annual approval of a study
2. Amendments to protocols, consent forms, and investigator drug brochures
3. Study closure
4. Other submissions, in which the potential impact on subjects is judged to be minimal by the HREC Chair and/or Manager Human Research Ethics Office, may also be classified as a Category B submission.

The HREC reserves the right to require full Committee review for any project. In addition, if significant problems are identified during the review of a Category B submission, the submission will be referred to the next available agenda for full committee review.

All Category B decisions will be reported to the full Committee at the first available meeting following the review and decision.

Enquiries regarding submissions may be made to the Uniting*Care* Health HREC, The Wesley Hospital, 451 Coronation Drive, Auchenflower 4066. Tel 07 32327500. Email ethics@uchealth.com.au.

Review Process:

Submissions are reviewed for scientific and ethical acceptability according to the standards of the National Statement and other regulatory and ethical guidelines as appropriate. In some cases, the Committee may solicit an external review, in consultation with the investigator, if additional input is considered necessary for appropriate review or the Committee may defer for more information from the Principal Investigator.

Following review, the protocol and consent form will be given one of three ratings as described below. The principal investigator will be notified in writing of the Committee's decision as well as the reasons for the rating. Requests for additional information or clarification of issues may be sought at that time.

Final Approval	No concerns with either the protocol or the consent form. The investigator has ethical approval to proceed with the study.
Conditional Approval	Questions remain about the protocol, itself, documentation may not be present, or, major revisions are required to the consent form. This rating does not indicate permission to commence the study. Revisions must be submitted to the Ethics Office for re-review by the Manager UCH Human Research Ethics Office or the full Committee for final approval prior to commencement of the research.
Not Approved [Major Concerns to Be Addressed]	Major methodological or ethical questions exist. The requested changes must be resubmitted and reviewed by the full Committee. The investigator will be invited to the next meeting to provide an opportunity to reply to the review before the HREC makes a final decision.
Not Approved [Final]	Major methodological or ethical questions continue to exist. The research is not approved and may not be conducted in its current form. No further consideration of the project in its current form is available.

Ongoing Requirements and Involvement of the HREC:

To help fulfil the responsibility for ongoing monitoring of research as indicated in the National Statement, after approval of the protocol researchers are required to:

1. Complete and return the "Annual Report" form (for all ongoing research) on a yearly basis;
2. Cooperate with audits, which can include monitoring of informed consent, and monitoring of adherence to protocol;
3. Complete and return "Application for Amendment" form when the researchers propose to make any change in the research protocol or consent form (HREC must approve any changes);
4. Inform the HREC immediately when the researchers believe the risks of research participation have changed, or an unanticipated scientific or ethical concern has been raised by the research staff or subjects;
5. Do all "Reporting of Serious Adverse Events" in accordance with HREC policies and procedures and relevant national and international regulations;
6. Submit "Updated Investigator's Brochure and/or Product Monograph" when any changes occur.
7. Complete and return the "Notification of Study Closure or Premature Termination" form when the study has been closed.
8. Investigators shall notify the Uniting*Care* Health HREC of any planned audits by external regulatory agencies (i.e. Queensland Health; Medical Board of Queensland). A copy of any report shall be sent to the HREC within 14 days of receipt by the investigator
9. Investigators shall notify the HREC of any planned audits by the sponsor. A report of any substantive findings shall be sent to the HREC within 14 days of the audit completion. This requirement refers to full site audits by the sponsor, not the on-going monitoring visits performed during the course of the study.

Serious Adverse Event Monitoring

Serious adverse event monitoring includes the following procedures:

1. Serious adverse events should be reported to the HREC office as soon as possible. The HREC will review any recommendations and evidence from the sponsor and investigator on these events in terms of the implications for patient safety and any changes needed to the protocol or consent form.

2. All summary reports on adverse events produced by the sponsor or review by independent data safety monitoring boards should be provided to the HREC for review.

Inquiries:

All submissions and inquiries should be directed to:

UnitingCare Health Human Research Ethics Committee
The Wesley Hospital
PO Box 499
Toowong Qld 4066

Telephone 07 32327500
Email ethics@uchealth.com.au