

**METRO NORTH HEALTH SERVICE DISTRICT
REDCLIFFE-CABOOLTURE HUMAN RESEARCH ETHICS COMMITTEE (HREC)**

TERMS OF REFERENCE

The Redcliffe-Caboolture HREC is a committee established by Queensland Health (QH) that is constituted and functions in accordance with the NHMRC “National Statement on Ethical Conduct in Human Research” 2007 (National Statement) and in accordance with the guidance of *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 [name] Hospital HREC facilitates the review and oversight of Human Research to protect the mental and physical welfare, rights, dignity and safety of participants in research and to promote ethical standards of human research in QH.

The Redcliffe-Caboolture HREC may obtain expert decision to provide scientific/technical assessment on research protocols and evaluation of research studies and compliance with regulatory requirements.

The Redcliffe-Caboolture HREC shall: (National Statement section 5.1.26)

- (a) Advise the Redcliffe & Caboolture Hospitals, through the [District CEO or delegate], of the ethical acceptability of research protocols submitted for consideration.
- (b) Maintain a Research Ethics Database for all research protocols submitted to the Redcliffe-Caboolture HREC, which would include monitoring and reporting requirements and any ongoing approval status of proposals.
- (c) Provide an annual report for Redcliffe-Caboolture Ethics Committee through the [District CEO or delegate], QH.
- (d) Apply for and maintain registration with the National Health and Medical Research Council (NHMRC) and the Australian Health Ethics Committee as a compliant human research ethics committee.

Relationships

The Redcliffe-Caboolture HREC will:

1. Report to the [District CEO or delegate] of Redcliffe & Caboolture Hospitals.
2. Have the right to charge fees to the sponsors of commercial research both for the processing and consideration of the protocols and for the monitoring of the research.
3. Review and approve research which may then facilitate expedited HREC approval at other participating Health Service District/s subject to individual HREC site specific requirements and expedited review procedures.

HREC Procedures:

- (a) Composition and Appointment: (National Statement sections 5.1.29 - 5.1.34)

The membership of the Redcliffe-Caboolture HREC will be constituted according to 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.”
- Members will attend continuing education and training in research ethics at least every three years (National Statement 5.2.3 (c)).
 - Membership appointments to the Redcliffe-Caboolture HREC will be considered for review every three years (National Statement 5.1.34).

(b) Protocols

- The Redcliffe-Caboolture HREC will normally require submissions to be in a standard format using the National Ethics Application Form (NEAF).
- Submissions may be made preferably in electronic form.
- The Chair and Secretariat will determine if any expert advice is required.

(c) Meetings: (National Statement sections 5.1.37 and 5.2.28)

- Meetings will be held every two months.
- Notice of meeting will be given at least two (2) weeks before any meeting.
- An electronic copy of the Protocols for consideration, including the NEAF, patient information & consent form, questionnaires or other relevant correspondence (where applicable) and the written advice for any meeting will be forwarded to all members at least one (1) week before the meeting.

(d) Meeting Protocol: (National Statement sections 5.1.30, 5.2.28 – 5.2.31)

- The Redcliffe-Caboolture HREC will only review completed NEAF applications submitted with a completed Site Specific Assessment form from January 2009.
- Decisions by the Committee about whether the research project meets the requirements of the National Statement must be informed by the exchange of decisions from each of the members that constitute the minimum membership of the Redcliffe-Caboolture HREC.
- 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 decision from a committee member unable to attend a face to face meeting will be considered along with those decisions 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 decision via submission to the Chairperson or Secretariat prior to the meeting.
- Meetings will normally be held in the Lecture Room 2 of The Redcliffe Hospital.
- The principal investigator or a representative for the investigator may be invited to attend the relevant meeting to discuss a proposal but would be required to leave the meeting before any decision is taken.

- Members of the committee associated with a research protocol being considered by the committee will be excluded from the meeting for consideration of that particular proposal.
- 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.
- In general, decisions of Redcliffe-Caboolture HREC will be reached by general agreement rather than simple voting majorities.
- The appointed Chairperson will chair every meeting when present. On occasions when the Chairperson is absent or excluded because of a conflict of interest, the meeting will appoint a chair.

(e) Secretarial Support:

- Secretarial support will be provided staff of the Office of the Human Research Ethics Committee, Metro North HSD, Redcliffe-Caboolture HREC.
- The minutes of meetings will be kept by the Secretariat of the Human Research Ethics Committee, Metro North HSD, Redcliffe-Caboolture HREC.
- 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.
- Draft minutes will be forwarded to the Chair as soon as practical after the meeting.
- Action following decisions recorded in the draft minutes will be initiated no sooner than 48 hours after circulation of draft minutes. Members who object to the progress of any actions recorded should contact the secretariat within that time frame.
- As much as possible, electronic communication will be used to communicate with members and Researchers.
- Advice to applicants regarding the ethical consideration and approval of protocols will include details of reporting requirements and monitoring processes.
- A copy of any advice to the research applicant will be forwarded simultaneously to the chairs of HREC's of all facilities in which the research will be conducted.

(f) Monitoring: (National Statement Chapter 5.5)

The Redcliffe-Caboolture HREC requires the Researcher to:

- Keep adequate records and provide access to the Redcliffe-Caboolture HREC when requested.
- Provide progress reports at intervals specified by the QHREC and at completion of any research at no less than an annual report
- Notify the HREC of significant events, side effects or complications occurring at any time during the research including the course of action taken.
- Notify the HREC of any complaints received from participants, staff, observers or the community.
- Provide prospective advice of any proposed changes to be made to the protocol and approval of these prior to implementation.
- Notify the HREC if the research is to be discontinued before the expected date of completion.
- Provide a copy of published results, presentations at conferences etc. to the HREC.

The Redcliffe-Caboolture HREC may:

- Request an interview with the researchers if required.
- Request access to research data and records if required.
- Request the decision of external experts if considered necessary.

(h) Handling Complaints regarding research misconduct and/or fraud: (Code of Conduct section 10 and National Statement section 5.6)

- A copy of the complaints may be received by the secretariat of the Redcliffe-Caboolture HREC
- The complaints should be forwarded to the appropriate HOD/Supervisor or CEO within the institution
- Any complaints received by the researcher must be forwarded to the appropriate HOD/Supervisor or CEO
- If the matter is not resolved it is then referred to the 'Designated Person' (as defined in Code of Conduct Section 10.2)
- The designated person should be a senior member of the institution's management structure who is experienced in research and research management. The designated person must not be the CEO.
- If the allegation is not resolved the complaint is referred for internal/external inquiry by panel or tribunal
- If the allegation is upheld advice is provided to the HOD/supervisor/ CEO regarding formal disciplinary action.
- An HREC is not usually involved in conducting inquiries into cases of research misconduct and fraud but may be called upon to give advice.

(g) Handling Complaints regarding HREC process:

- A copy of the complaints will be received by the secretariat of the Redcliffe-Caboolture HREC who will monitor the complaints.
- Any complaints received by the researcher must be forwarded to the Chairperson or Secretary, Redcliffe-Caboolture HREC. Consent forms must include contact details to allow such complaints to be made.
- Complaints on the process, conduct or decisions of the Redcliffe-Caboolture HREC should be made in writing to the Chairperson or Secretary of the HREC.
- All complaints will be acknowledged within seven (7) days.
- The Chairperson of Redcliffe-Caboolture HREC will determine action to be taken. This may necessitate a special meeting of the HREC, which may be called without the usual 14 day requirement for notice, to consider such a complaint.
- The complainant will be advised of the decision of the Redcliffe-Caboolture HREC within 30 days.
- If the complainant does not accept the decision of the Redcliffe-Caboolture HREC, the complaint may be forwarded to the [District CEO or delegate], Redcliffe & Caboolture Hospitals whose decision will be final.