

Human Research Committee Ethics (QCTN HREC) (Quorum 7)

The Queensland Clinical Trials Network Inc. Human Research Ethics Committee (QCTN HREC) abides by the guidelines of the National Health and Medical Research Council's *National Statement on Ethical Conduct in Human Research, 2007*.

Terms of Reference

1. **Title:**
 Queensland Clinical Trials Network Inc. (QCTN) Human Research Ethics Committee (HREC).

2. **Scope of responsibilities for ethical review:**
 - a. For any application where the QCTN HREC is not an accepting HREC in multi-centre Research it will consider the ethical implications of proposed human research with participants proposed by Institutions/Investigators and to advise collaborating Institutions/Investigators of the ethical acceptability of these proposals (Section 5.3 *National Statement on Ethical Conduct in Human Research, 2007*).
 - b. Monitor experiments involving human research approved by the QCTN HREC to completion to ensure compliance with approved ethical standards. Monitoring will be limited to that described in the HREC services agreement and may include:
 - i. Receiving reports of Serious Adverse Events;
 - ii. Receiving progress reports;
 - iii. Undertaking site visits (as required);
 - iv. Considering study amendments;
 - v. Considering study extensions;
 - vi. Considering declarations of pecuniary interest from Investigators;
 - vii. Advising Institutions/Investigators of a withdrawal of a favourable opinion.
 - c. In carrying out these functions the QCTN HREC is to:
 - i. Conform with the National Statement (as amended);
 - ii. Ensure that procedures for obtaining consent are observed;
 - iii. Ensure that no members of the QCTN HREC adjudicate on proposals in which they may be personally involved or otherwise conflicted; and
 - iv. Ensure that, while accepting that researchers have a duty to advance knowledge by human research, the rights of the individual volunteers, or subjects of research, take precedence over the expected benefits to human knowledge or the QCTN.

3. **Relationship to non-affiliated researcher:** The QCTN HREC will consider projects from Institutions/Investigators that abide by the QCTN HREC Services agreement (as amended from time to time).

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4. **Institutional accountability:** The HREC services agreement will document an agreement between the Institution/Investigator and the QCTN and will define the approval, conduct and monitoring of research.
5. **Mechanisms for reporting:** The QCTN HREC will report to the National Health and Medical Research Council (NHMRC) annually or as required and is responsible to the QCTN Management Committee.
6. **Categories of minimum membership:** The QCTN HREC is constituted in accordance with the National Statement. It comprises the following persons as a minimum:
 - a. Chairperson with suitable experience and whose other responsibilities will not impair the HRECs capacity to carry out its obligations under the National Statement;
 - b. An executive of the QCTN;
 - c. At least two lay people, one man and one woman, who have no affiliation with the institution and do not currently engage in medical, scientific, legal or academic work;
 - d. 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;
 - e. At least one person who performs a pastoral care role in a community, for example, an Aboriginal elder or a minister of religion;
 - f. At least one lawyer, where possible one who is not engaged to advise the institution; and
 - g. At least two persons 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.
 - h. The Secretariat (Executive Secretary, Minute Secretary and administrative support) is provided by the QCTN.
7. **Fees Policy: See FORM-HREC-018** Fee Schedule of fees for the Queensland Clinical Trials Network Inc. HREC
8. **Remuneration of members:** QCTN HREC members will be remunerated at a rate of \$400 per meeting where at least one protocol, and up to six (6) protocols, is reviewed and \$800 per meeting where seven (7) and up to ten (10) protocols are reviewed, as agreed by the QCTN. QCTN has the right to vary this remuneration from time to time.
9. **Quorum:**
 - a. A quorum exists if seven of the eight members appointed to the QCTN HREC are present.

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- b. A decision of the QCTN HREC is made by a majority (at least 4) of the members present and voting for the decision at the meeting. The decision as to whether there is an appropriate cross-section of members present at any particular meeting will be made by the Chair in consultation with those present at the meeting. However, the positions required by the National Statement must be represented when an ethical consideration is made.
 - c. The Chair (or presiding Chair) has a deliberative vote and also has a casting vote in the event of an equality of votes by non-conflicted members present.
 - d. Where there is less than full attendance at a meeting, the Chair must be satisfied before a decision is reached that the National Statement minimum membership have received all papers and have had an opportunity to contribute their views and that these have been recorded by the Executive Secretary and considered by the members present.
 - e. If the minimum requirements have not been satisfied, the HREC may not commence, continue or conclude any discussion with the purpose of determining the QCTN HREC's opinion on an application for ethical review.
 - f. The QCTN HREC meeting, may proceed with any other business on the agenda as if it were a sub-Committee meeting, provided that the Chair (or acting Chair) and at least one other member is present.
 - g. A member who submits written comments but does not attend the meeting counts towards the Quorum.
10. **Frequency of Meetings:**
- a. The QCTN HREC will meet monthly or as determined by the QCTN HREC Chair and advised in writing by the CEO of QCTN on the QCTN website (www.qctn.com.au).
 - b. A decision is to be provided to the Institution/Investigator within 60 days, excluding stop clock periods while the QCTN HREC awaits advice from the Investigator.
11. **Confidentiality:**
- a. All members of the QCTN HREC are required to sign a non-disclosure agreement and treat applications as commercial in confidence.
12. **Conflict of interest:**
- a. During meetings, the Chair will request from each HREC member a declaration setting out all direct or indirect interests, pecuniary or otherwise in a matter being considered, or about to be considered.
 - b. Disclosure must include interests that could be perceived to represent a possible conflict of interest.
 - c. At the discretion of the Chair, QCTN HREC members with a declared conflict of interest may attend the HREC meeting up to the point that the Chair calls for a decision on the research proposal from the HREC.

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- d. Before a decision is made, the Chair is required to ask the QCTN HREC members with a declared conflict of interest to leave the room while the decision is made. No member of the QCTN HREC may adjudicate on research in which that member has any conflict of interest including any personal involvement or participation in the research, any financial interest in the outcome or any involvement in competing research.
 - e. An Investigator must disclose to the QCTN HREC the amount and sources of potential sources of funding for the research and must declare any affiliation or financial interest when proposing and when reporting the research. The QCTN HREC must consider the extent to which it should disclose information about funding sources.
 - f. All interests are documented in the minutes of the meeting.
13. **Delegation of authority for expedited review or exemptions:** Research involving more than low risk cannot be considered for expedited review or exemption.
- a. The following types of research require review by a full HREC:
 - i. All research that involves more than low risk;
 - ii. Research falling under the following chapters of the National Statement (except research on collections of non-identifiable data under these chapters that have negligible risk):
 - iii. Chapter 3.3: Interventions and therapies including clinical and non-clinical trials and innovations;
 - iv. Chapter 3.5: Human genetics;
 - v. Chapter 3.6: Human stem cells;
 - vi. Chapter 4.1: Women who are pregnant and the human foetus;
 - vii. Chapter 4.4: People highly dependent on medical care who may be unable to give consent;
 - viii. Chapter 4.5: People with a cognitive impairment, an intellectual disability or a mental illness;
 - ix. Chapter 4.7: Aboriginal and Torres Strait Islander peoples; and
 - x. Some categories of research falling under Chapter 4.6 People who may be involved in illegal activities. In particular research that is intended to study or expose illegal activity or that is likely to discover it.
 - b. Examples of situations which may qualify for expedited review include:
 - i. Social science questionnaires on non-controversial, non-personal issues;
 - ii. Observational studies in public situations which focus on non-sensitive issues;
 - iii. Studies of existing non-identified data, documents, records, pathological or diagnostic specimens;
 - iv. Studies that do not involve an intervention that could result in significant harm to participants;
 - v. Studies that are substantially similar to another study already approved.

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- c. It should be noted that any of the above situations has the potential to become sensitive and may therefore require review by a full HREC meeting at the Chair's discretion.
- d. Human research outside the chapters of the National Statement listed above that is on collections of non-identifiable data and poses negligible risk may be exempted from ethical review.

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