Metro South HREC
TERMS OF REFERENCE

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PURPOSE:

The Metro South Human Research Ethics Committee (HREC), (EC00167) at the Princess Alexandra Hospital within Metro South Hospital and Health Service is constituted and functions in accordance with the National Health & Medical Research Council (NHMRC) "*National Statement on Ethical Conduct in Human Research (2007)"* and complies with the "*Australian Code for Responsible Conduct of Research (2007)* and the Queensland Health (*QH) Research Management Policy and Framework (QHRMP; 2010).*

The HREC acts in a consultative and advisory capacity with researchers to ensure that all clinical, research and management practices are conducted in an ethical and scientifically robust manner. Key objectives of the HREC are to:

- Safeguard the mental and physical welfare, rights, dignity and safety of participants involved in human research;
- Facilitate and promote high calibre ethical research through efficient and effective review processes; and
- Ensure that all clinical and health research is conducted responsibly and in the interests of the wider community.

1. Scope of Responsibilities and Functions (National Statement section 5.1.27)

The Metro South HREC is appointed by and acts in an advisory capacity to the Metro South Hospital and Health Service. The Committee considers all research protocols involving humans across the total breadth of health services provided at the Princess Alexandra Hospital, Logan and Beaudesert Hospitals, Redland Hospital and Queen Elizabeth II Jubilee Hospital, as well as Community and Primary, Oral and Mental Health Facilities within the Metro South Hospital and Health Service.

The Metro South Chief Executive or Delegate, upon recommendation of the Committee, may grant approval for research proposals conducted within its facilities. Furthermore the Committee reviews multi-centre research from other Hospital and Health Services, Jurisdictions and practices (including private health facilities). The Committee has been certified by the NHMRC to conduct reviews of Australian Multi Centre Research and participates in the Queensland Health single ethical review process. To this end the Metro South HREC aims to:

- Provide balanced, independent and timely review of research protocols involving human participants in respect to their ethical acceptability and scientific merit.
- Review and recommend approval of research which may facilitate expedited HREC approval at other participating Hospital and Health Service/s subject to individual HREC site specific requirements and low risk expedited review procedures.
- Oversee approved protocols during the course of the research until completion to ensure that they comply with approved ethical standards, legislation, codes of practice and policies. Specific monitoring of the conduct of research will be conducted via the Research Governance Office (RGO) and in the case of multi centre research, the Co-ordinating Principal Investigator at the respective Institution.

- The HREC may obtain expert opinion or establish sub-committees to provide scientific/technical assessment and safety evaluation of research protocols along with compliance with regulatory requirements.

- The Research Ethics Secretariat will register all research protocols submitted to the Metro South HREC along with any monitoring and reporting requirements and approval of protocol amendments during the course of the research.

2. Relationships and Reporting

The Metro South HREC (previously the Princess Alexandra Hospital HREC) established by the Institution in keeping with the National Statement (2007 section 5.1.26) will:

- Report to the Metro South Hospital and Health Service (HHS) Chief Executive via the Chair of Centres for Health Research, Princess Alexandra Hospital. Formal mechanisms of reporting include the HREC Annual Compliance Report to the Australian Health Ethics of the National Health and Medical Research Council (NHMRC), minutes for all HREC meetings signed off by the Chairperson, six-monthly Executive reports, monthly meetings, and an annual report for the Centres for Health Research Report.

- Review and recommend approval of all research undertaken within and in collaboration with the Metro South HHS along with multicentre research to be conducted in other Hospital and Health Services, Jurisdictions and practices.

- Review and recommend approval of research which may facilitate expedited HREC approval at other participating HHS, subject to individual site specific requirements and to expedited review procedures.
- Oversee the monitoring of approved research until completion and the provision of final reports to ensure that the research has complied with approved ethical standards along with relevant legislation, codes of practice, policies and regulations.

3. HREC Composition and Appointment (National Statement sections 5.1.29 – 5.1.34)

The membership of the HREC is constituted according to the National Statement and includes the following:

a) Chair, 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 woman, 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. Such 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 HREC will be considered for review every three years *(National Statement 5.1.34).* Recommended reappointments of individual members will be made by the HREC Chairperson to the Metro South HHS Chief Executive for approval.
- Prospective members of the HREC may be recruited by direct approach, nomination or by advertisement.
- Members will be provided a letter of appointment including the date of appointment, length of tenure, assurance that indemnity will be provided in respect of the conduct of their duties as an HREC member, HREC meeting attendance responsibilities and general responsibilities as an HREC member.

4. Confidentiality and Conflict of Interest (National Statement 5.4.5)

Members will be required to sign a declaration form undertaking that:

- Any conflicts of interest, which exist or may arise during tenure on the Metro South HREC will be declared, and

- All matters of which they become aware during tenure on the Metro South HREC will be kept confidential.

5. Induction, Mentoring and Training

New members are provided with an HREC Members' Induction Manual, attend initial meetings as an observer, and are provided individual mentoring via the Chair and from time to time other member/s of the HREC.

All members attend continuing education courses and training in research ethics and regulation (at least every three years). Throughout their tenure, members are given the opportunity to attend conferences and workshops, supported by the Institution, that are relevant to the roles and responsibilities of the HREC.

6. Remuneration

All HREC Members provide their services and expertise on a voluntary basis. All essential and necessary expenses incurred by members in carrying out their HREC duties will be reimbursed. The Chairs of both the HREC and the Low Risk Review Panel receive remuneration to compensate for the additional time required to both chair the meeting for the HREC and perform executive duties.

7. Committee Procedures

The Metro South HREC operates in accordance with written standard operating procedures (SOP). These procedures are reviewed at least every three years and updated as required. All HREC members have access to copies of the SOP, and from time to time, will be consulted with regard to amendments.

(a) Protocol Submissions

- The HREC requires submissions to be in a standard format using the National Ethics Application Form (NEAF) or the Queensland Low and Negligible Risk (LNR QLD) form available on the Online Forms Website.
- The HREC requires researchers to (i) electronically upload all supporting documents onto the online forms website and (ii) submit hard copies of the protocol and associated study documentation.
- The Chair along with Committee members will determine if any additional expert advice is required in relation to scientific review.

Before giving a favourable opinion, the HREC should be adequately reassured about the following issues (as applicable):

- Scientific design and conduct of the study;
- Recruitment of research participants;
- Care and protection of research participants;
- Protection of research participants' confidentiality;
- Informed consent process; and
- Local community considerations.

All submissions should adhere to the values and principles of ethical conduct as described in the National Statement on Ethical Conduct in Human Research (2007):

- Research merit and integrity
- Justice
- Beneficence
- Respect

(b) Levels of Ethical Review

- ***Low & Negligible Risk Research (National Statement Section 2 & Section 5.1.20-5.1.23)***
  Research that carries only negligible risk and involves the use of existing collections of data or records that contain only non-identifiable data about human beings may be exempted from full ethical review. The National Statement (2007) recognises that the levels of ethical review for low risk and negligible risk research may include, but need not be limited to:
  a. review or assessment at departmental level by the head of department;
  b. review or assessment by a departmental committee of peers (with or without external or independent members);
  c. delegated review with reporting to an HREC; or
  d. review by a subcommittee of an HREC.

  In keeping with the National Statement the Metro South HREC provides review of low risk research protocols via a Low Risk Review Panel comprised of the Low Risk Chair and two nominated HREC members with expertise/understanding relevant to the nature and scope of the research and participants to be recruited. The Low Risk Chair will recommend approval of the low risk protocol, to be ratified by the HREC at

the next meeting and final approval (including the Site Specific Assessment) will be signed off by the Chief Executive Officer. .

Research Identified as Higher than Low Risk Any research identified as involving more than low risk must be referred to the HREC for full review, except in exceptional circumstances as stated below.

- ***Multicentred research studies reviewed and approved by another HREC***
  The HREC may approve a protocol without further ethical review, which another ethics committee has approved and the protocol appears to conform to the requirements of the HREC. The HREC reserves the right to ratify the previous decision, instigate its own review process, request amendments, or clarification, or reject the protocol. The institution will accept the reviews of other QH Certified HRECs.

- ***Exceptional circumstances exempt from full ethical review***
  In exceptional circumstances, where as a matter of public policy, and in the national interest, it is essential that an application should be reviewed urgently (to allow health-related research to commence as quickly as possible), the Metro South Chief Executive or Delegate may grant approval under exceptional circumstances for a protocol where:

  - Another Committee has approved the protocol and the protocol appears to conform to the requirements of the HREC; and
  - Clinical need necessitates urgent approval of the protocol.

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

- Meetings will be held monthly, except for January when there will be no scheduled meeting.
- Meeting dates are available on the Centres for Health Research - Research Ethics and Governance website.
- Notice of meetings will be given to members for the current year and at least two (2) weeks prior to a meeting.
- A copy of the agenda, previous minutes, new protocols for consideration, including the NEAF, patient information and consent form, questionnaires or other relevant correspondence (where applicable) , along with any other papers relevant to the meeting, will be forwarded to all members two weeks prior to the meeting.
- In addition, documents relevant to all new applications will be uploaded, by the Secretariat, to the AU Red Member's Portal. In conjunction with distribution of hard copy agenda materials, the Secretariat will alert HREC members to the fact that documents have been made electronically available for access and review. Members are then asked to submit, to the Members' Portal, their assessment/comments in respect to all new applications; prior to the meeting. These comments are collated by the Secretariat and incorporated into a final set of HREC minutes.

(d) Meeting Protocol (National Statement sections 5.2.1-5.2.4, 5.2.28 – 5.2.31)

- Decisions by the HREC as to whether the research protocol meets the requirements of the National Statement must be informed by the exchange of opinions from each of the members that constitute the minimum membership of the HREC.

- Where there is less than full attendance of the minimum membership at a meeting, the Chair must be satisfied, before a decision is reached, that those members unable to attend the meeting have received all papers and have had an opportunity to contribute their views and that the views of all members have been recorded and considered. Members who are unable to attend a meeting are asked to contribute and advise their opinion via submission to the HREC Coordinator prior to the meeting.
- Meetings are held in the Translational Research Institute on Level 2, Princess Alexandra Hospital. Teleconference linkage to individual members unable to be present in person will be acceptable, if required.
- 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 will be required to declare any conflict of interest (real or perceived) prior to or at any time during a meeting, such as when the member is associated with a research protocol under review by the Committee. The Committee will determine the action to be taken including excluding the member from the meeting during deliberation of the particular protocol.
- In general, decisions of HREC will be reached by a consensus rather than simple voting majorities.
- The appointed Chair will chair every meeting when present. When the Chair is absent or excluded because of a conflict of interest, the HREC will appoint a Chair from attendees at the meeting if a Deputy Chair is unavailable. .

(e) Secretariat Support

Secretariat support will be provided by staff of the Centres for Health Research.

(f) Decisions from HREC meetings

Minutes will record major issues discussed, concerns expressed, decisions taken and reasons for rejection or requirement for change to the protocol and where necessary link those reasons to the National Statement. Notification of the Committee's deliberations will be made directly to the Principal Investigator (the HREC does not engage in direct communication with sponsors unless in exceptional circumstances and with the agreement of the Principal Investigator).

(g) Post HREC Approval Process

- ***Site Specific Assessment (SSA)***
  The SSA is an institutional research governance requirement. It involves assessing the suitability of a site at which the research is being conducted and identifying whether the 'actual' and or 'in kind' resources required for the conduct and completion of the project can be met by the Metro South Hospital and Health Service. Research ***can only*** commence at a site upon authorisation by the Metro South Chief Executive or Delegate (including sign-off of SSA).

- ***Public Health Act (PHA) application***
  If the research involves access to confidential information held by Queensland Health then a PHA application may be required under Section 281 of the Public Health Act 2005. This is submitted through the Office of Health and Medical Research by the researcher, for sign off by the Director-General / Director-General delegate, after HREC approval is given.

- Queensland Civil and Administration Tribunal ***(QCAT) application***
  If the research involves persons with impaired decision making capacity, an application to the Queensland Civil and Administration Tribunal (QCAT) for approval to conduct clinical research will need to be submitted. This is submitted by the researcher, after HREC approval is given.

- ***Progress Reports***
  Progress reports on all approved research protocols are to be submitted to the HREC at least annually. The first annual report should be submitted 12 months after the date on which the approval was given. The Committee may request more frequent progress reports, primarily based on the level of risk associated with the particular research protocol.

- ***SAE Reporting***
  All researchers must comply with the NHMRC National Monitoring Framework for the reporting of SAEs and SUSARS in clinical trials as detailed in the Metro South HREC guidelines and website information.

(h) Insurance and indemnity for HREC members

As per the National Statement on Ethical Conduct in Human Research Section 5.1.9 the Metro South HHS provides HREC members with indemnity under Queensland Government Insurance Fund insurance policy.

(i) Storage of data

Data may be collected, stored or disclosed in three mutually exclusive forms:

- *Individually identifiable data*
  The identity of a specific individual can reasonably be ascertained. Examples of identifiers include the individual's name, image, date of birth or address;
- *Re-identifiable data*
  Identifiers have been removed and replaced by a code, but it remains possible to re-identify a specific individual by, for example, using the code or linking different data sets;
- *Non-identifiable data*
  Data which have never been labelled with individual identifiers or from which identifiers have been permanently removed, and by means of which no specific individual can be identified. A subset of non-identifiable data is that which can be linked with other data so it can be known that they are about the same data subject, although the person's identity remains anonymous.

The NHMRC National Statement on Ethical Conduct in Human Research 2007) avoids the term 'de-identified data', as its meaning is unclear. While it is sometimes used to refer to a record that cannot be linked to an individual ('non-identifiable'), it is also used to refer to a record in which identifying information has been removed but the means still exist to re-identify the individual. When the term 'de-identified data' is used, researchers and those reviewing research need to establish precisely which of these possible meanings is intended.

(j) The National Ethics Application Form (NEAF)
In keeping with the National Statement on Ethical Conduct (2007) the Metro South HREC uses the NEAF application form as its core document for full review of research protocols, completed online by the researcher and submitted to the HREC Coordinator. The NEAF and its supporting documentation, such as the participant information sheet, consent form(s) and the protocol serve to inform the Committee regarding the ethical aspects and scientific merit of the protocol.

8. Monitoring (National Statement Chapters 5.5 & 3.3)

Both the Institution and the HREC act in accordance with the National Statement in relation to monitoring approved research and require the Principal Researcher (including Co-ordinating Principal Investigator for multi-centre research) to:

- Keep adequate records (hard copy and/or electronic) and provide access to the HREC when requested.
- Provide annual progress reports at intervals specified by the HREC and at completion of any research.
- Notify and provide reports, in a timely fashion, to the HREC of significant events (including SAEs and SUSARs), complications and protocol violations that occur at any time during the conduct of research, detailing the course of action taken. Where relevant, Principal Investigators will notify the outcome of monitoring visits by trial sponsors. In relation to sponsored clinical trials and investigator initiated trials involving drug or device interventions the notification of adverse events should be in keeping with the NHMRC Monitoring Framework.
- Provide prospective advice of any proposed changes to be made to the protocol and obtain approval of these changes prior to implementation.
- Notify the HREC if the research is to be discontinued before the expected date of completion (detailing a justification for the termination of the trial, such as closure of the trial by the pharmaceutical sponsor).
- Notify the HREC of any complaints received from participants, staff, observers or the community.
- Provide documents of the outcomes of the research to the HREC.

The HREC may:
(a) Request an interview with the researchers if required.
(b) Request access to research data and records (including consent documentation as part of a random audit).
(c) Request the opinion of external experts if considered necessary.
(d) Liaise with the local site Research Governance Office.

9. Complaints (National Statement Chapter 5.6)

In keeping with the National Statement and the *"Australian Code for the Responsible Conduct of Research 2007"* the institution recognises the A/Director, Research Development and Ethics, Centres for Health Research, as the "designated person" for handling of research complaints in consultation with the Chair of the HREC, including research misconduct.

- In the first instance all complaints will go to the Chair of the HREC via the HREC Coordinator for consultation with the HREC.
- Any complaints received by the researcher must be forwarded to the Chair of the HREC via the HREC Coordinator.
- Consent forms must include contact details of the HREC Coordinator to ensure such complaints can be communicated.
- Complaints on the process, conduct or decisions of the HREC should be made in writing to the Chair of the HREC via the HREC Coordinator. The Chair of 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.
- All complaints will be acknowledged within seven (7) days. The complainant will be advised of the decision of the HREC within 30 days. If the complainant does not accept the decision of the HREC, the complaint may be communicated by the Chair to the Metro South Chief Executive for further consideration.
- Any concerns, complaints or allegations about the conduct of a research protocol will be recorded in a register and to the local site Research Governance Officer. Processing of research complaints regarding the HREC review process will be as per the Queensland Government Department of Health HREC Administrators SOP and will also be recorded in a register.

10. Amendment to the Terms of Reference

Terms of Reference may be amended from time to time by following the procedure below:

- The proposal must be in writing and circulated to all HREC members for their consideration to allow for the views of members to be discussed at the next scheduled meeting of the HREC for ratification.
- Proposed amendments may be made by a member of the HREC.
- The amended terms of reference will be sent by the Chair to the Director Research Development and Ethics for forwarding to the Metro South Chief Executive.

KEY DOCUMENTS AND WEBSITES

National Statement on Ethical Conduct in Human Research (2007)

http://www.nhmrc.gov.au/publications/synopses/e72syn.htm

Australian Code for the Responsible Conduct of Research (2007)

http://www.nhmrc.gov.au/publications/synopses/r39syn.htm

Note for Guidance on Good Clinical Practice (CPMP/ ICH / 135 / 95)

http://www.tga.gov.au/pdf/euguide/ich13595.pdf

World Medical Association Declaration of Helsinki - Ethical Principles for Medical Research Involving Human Subjects

http://www.wma.net/en/30publications/10policies/b3/

Health and Medical Research Unit, Office of Health & Medical Research, Qld Health

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