1 TERMS OF REFERENCE

The purpose of this document is to outline the terms of reference, including the role, responsibilities, composition and operating guidelines of the QIMR Berghofer Medical Research Institute (the Institute) QIMR BERGHOFER HUMAN RESEARCH ETHICS COMMITTEE (the HREC).

2 PURPOSE

2.1 The HREC is a committee established by the Council of the Queensland Institute of Medical Research (the Council), to ensure maintenance of ethical standards in research and compliance with regulatory guidelines and The National Statement on Ethical Conduct in Research Involving Humans 2007, updated 2018 (the National Statement).\(^1\)

2.2 The Institution is accountable for its HREC to the National Health and Medical Research Council (NHMRC) under registration requirements (NHMRC Registration No: EC00278), and through NHMRC certification as a lead HREC under the National Approach to Single Ethical Review of Multi-Centre Research. The Committee is established and practises in accordance with the National Statement. The Committee is certified for single ethical review of studies involving adults: specifically, for Phase I, II, III & IV clinical trials; population health; clinical interventional research other than clinical trials; qualitative health, mental health, health services, and molecular biology research.

3 AUTHORITY

3.1 The HREC is accountable to and reports to the Council.

3.2 The HREC is assisted by the Human Scientific Subcommittee (HSSC) and the Clinical Trial Protocol Committee (CTPC). These Subcommittees provide advice on scientific, technical and clinical aspects of human research protocols and clinical trials, and on compliance with regulatory requirements. Both Subcommittees are appointed by the HREC and the Director and CEO of the Institute.

3.3 The subcommittees report to the HREC with respect to the review of human research.

4 ROLES AND RESPONSIBILITIES

4.1 Role of the HREC

The functions of the HREC are to:

a) Advise the Council on policy requirements relating to the National Statement, and any other relevant State, Territory and Commonwealth legislation relating to human research.

b) Consider human research protocols carried out:

i. Within the premises of the Institute, including both the Institute and non-Institute scientific groups;
ii. By Institute personnel, whether intra- or extra-mural;
iii. By organisations for whom the Institute has agreed to act;
iv. By organisations, with whom the Institute has a Memorandum of Understanding;
v. By organisations beyond those with whom the Institute has established a Memorandum of Understanding, pursuant to mutual recognition arrangements

  c) Carry out ethical reviews and approve, request amendment of, or reject a research proposal on ethical grounds, monitor, review, and if necessary, suspend or withdraw approval for any research project.

d) Consider whether expert advice is required for the proper consideration of a particular proposal, and where required, the Committee may recommend to the Institute that an appropriate expert/s be commissioned to provide that advice.

e) Maintain a register of the research protocols submitted to the HREC.

f) Provide information and reports to the NHMRC and NHMRC principal committees on request.

g) Provide information and reports to the Therapeutic Goods Administration (TGA) of the Commonwealth Department of Health, where appropriate.

h) Where the conditions of a grant involve compliance with the requirements of any other regulatory agency, particularly an overseas agency, the HREC will endeavour to meet those requirements. Investigators should notify the HREC of the requirements before the grant is accepted.

4.2 Before granting approval to a research study involving humans, the HREC must be satisfied that the protocol conforms to:

a) The National Statement¹;

b) Where relevant, Integrated Addendum to ICH E6(R1): Guideline for Good Clinical Practice E6(R2) Nov 2016²;

c) Any requirements of relevant Commonwealth, State or Territory laws; and

d) Where relevant, overseas regulatory requirements.

4.3 Mechanisms of Reporting

Formal mechanisms of reporting include the following:

a) A summary of significant issues raised in the minutes of all HREC meetings and any urgent issues that required the Institute’s immediate action and/or attention is provided to the Director’s Executive Committee and the Council for consideration. A copy of the minutes is available to members online via Accellion.

b) The HREC Annual Report is provided to the NHMRC Australian Health Ethics Committee (NHMRC-AHEC).

c) Submissions are provided to Council as requested or as initiated by HREC.

5 MEMBERSHIP AND MEETINGS

5.1 Chair and Deputy Chair

- Both the Chair and Deputy Chair of the HREC are appointed by the Council.
- In the absence of the Chair, the Deputy Chair will perform the duties of the Chair.
- In the absence of both the Chair and Deputy Chair, the Chair may appoint an Acting Chair.

5.2 Secretary

- The HREC Secretary is an employee of the Institute.
• The Secretary, in consultation with the Chair, will prepare and send notices of meetings and agendas and accurately record all decisions of the Committee.
• The Secretary will table all correspondence, reports, submission and other information relevant to the Committee.
• The Secretary assists the Chairs of the HREC, HSSC and CTPC, and undertakes administrative tasks of the HREC and Subcommittees under the guidance of the Manager Ethics and Clinical Trials.
• The Secretary acts as a liaison between the HREC, its Subcommittees and the researchers.
• The Secretary provides administrative advice to the researchers on the Institute’s process of ethics review.

5.3 Membership

The HREC is established in accordance with the prescriptions set out in the National Statement (NS5.1.30) with a minimum membership of eight. As far as possible there should be equal numbers of men and women, and at least one third of the members should be from outside the Institute. The minimum membership is:

a) A Chair with suitable experience, whose other responsibilities will not impair the Committee’s capacity to carry out its obligations under the National Statement;
b) At least two lay people, one man and one woman, who have no affiliation with the Institute 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;
d) At least one person who performs pastoral care in a community, for an example, an Aboriginal elder, a minister of religion;
e) At least one lawyer, where possible one who is not engaged to advise the Institute; 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 experience.
g) No member may be appointed in more than one of the categories listed above.
h) The Institute should ensure the Committee has access to the expertise necessary to enable it to address the ethical issues arising from the categories of research it is likely to consider.

5.4 Appointment of Members

a) Vacancies on the committee may be advertised via newsletters and publications of the Institute and stakeholders such as Queensland Health, The University of Queensland, the Australian Institute of Company Directors, SEEK, etc.
b) Upon submission of a Curriculum Vitae and approval by the Chair (which will include an interview of the prospective member), the prospective member will be invited to attend the next HREC meeting as an observer. During this meeting the prospective member will have an opportunity to become familiar with committee procedures and workings. Subsequent to agreement from both parties (prospective member and Chair), a nomination for membership is sent to the Council for consideration.
c) HREC members are appointed by the Council. All changes to the membership are communicated to the NHMRC, the NHMRC-AHEC, and other official research regulatory bodies.
5.5 Period of Appointment
   a) A Committee member is normally appointed for a three-year term. A retiring member may be reappointed with a maximum total term of six years.
   b) The Chair is appointed for a three-year term. A retiring Chair may be reappointed for one additional term, with a maximum total term of six years, unless otherwise approved by the Council in writing.
   c) A Committee member who is subsequently appointed as Chair may serve for a maximum total term of nine years.
   d) Notwithstanding anything to the contrary in these Terms of Reference, the Chair of Council may, in their sole discretion, consent to the extension of an appointment beyond the applicable maximum term.
   e) Appointments to fill casual vacancies are for the balance of the original appointee’s term.
   f) Appointments may be terminated by either party after two months’ notice given in writing.

5.6 Conditions of Appointment
   a) Members are appointed as individuals for their knowledge, qualities, expertise and relevant experience, not as representatives of any organisation, group, or opinion.
   b) Before appointment, members acknowledge in writing their acceptance of the terms of reference of the Committee and any requirements for confidentiality, privacy and training or professional development required by the Institute.
   c) Members receive a formal notice of appointment and assurances that they will be covered by the Institute’s insurance policies as they relate to professional indemnity whilst performing the business of the Committee.
   d) Members undertake appropriate induction as outlined in the QIMR Berghofer HREC Member Induction Manual.
   e) Members attend continuing education or training programs in research ethics at least every three years.

5.7 Remuneration
   a) Council in its absolute discretion may elect to remunerate the Chair in recognition of the workload associated with meeting the responsibilities of the position, including preparation and follow-up actions for meetings. The Council will determine and approve the quantum of such payment in line with the Remuneration Procedures for Part-Time Chairs and Members of Queensland Government Bodies or any other government requirements.
   b) Other HREC members provide their services on a voluntary basis.
   c) All essential and necessary expenses incurred by members in carrying out their HREC duties will be reimbursed by the Institute, on production of original receipts.
   d) Internet access may be provided to the primary place of residence to members who are not staff of the Institute or co-located entities to enable review of electronic research protocols.
   e) Parking will be provided at Herston for members who are not QIMR Berghofer employees while attending to HREC business.
5.8 Ethical practices
Members are required to declare any interests that could constitute a real, potential or apparent conflict of interest with respect to participation on the Committee. The declaration must be made on appointment to the Committee and in relation to specific agenda items at the outset of each Committee meeting, and be updated as necessary.

5.9 Meetings and attendance
- The HREC will meet at least nine times per year.
- A quorum will consist of at least the minimum membership of eight as described in section 5.3.

6 COMMITTEE OPERATION

6.1 Written Proposals
a) The HREC reviews project applications submitted via the QIMR Berghofer Electronic Form (E-Forms) system or such other system as adopted by the Institute from time to time.
b) Human experimentation proposals (non-clinical trial) must conform to the requirements of the National Statement¹ and researchers must provide sufficient information required for scientific and ethical evaluation of the protocols.
c) In addition to the National Statement¹, Clinical trials protocols must conform to the requirements of the Integrated Addendum to ICH E6 (R1): Guideline for Good Clinical Practice E6(R2) Nov 2016² and researchers must provide sufficient information required for clinical evaluation of the protocols.
d) A copy of the full research protocol and associated documents for each project are recorded and available for review in the QIMR Berghofer Electronic Form system, or such other system as adopted by the Institute from time to time.

6.2 Alternate Review Pathways
a) Minimising duplication of ethical review
   i. The Institute may accept the ethical approval and oversight from another NHMRC-accredited HREC for research conducted by Institute Personnel (NS5.3)¹.
   ii. Submissions for a waiver must be accompanied by evidence that the other HREC has reviewed and approved the nature of the work occurring at the Institute. This may be a protocol or an alternative document, approved and listed in the original project approval letter. Governance oversight in the form of a Material Transfer Agreement (MTA) may still be required.
   iii. Applications for a waiver will be considered by the Chair who may request additional information or refuse a waiver if deemed unsuitable.

b) Low and Negligible Risk Research Protocols
   i. Applications for research that carry no more than low or negligible risk may be submitted for review to a scientific Subcommittee of the HREC, or to the HREC Chair (NS5.1.18 - 5.1.21)¹.
   ii. Applications determined to fit the definition of low or negligible research as defined in the National Statement (NS2.1.6 – 2.1.7)¹, may be approved by the HREC Chair or scientific Subcommittee without being reviewed by the HREC.
iii. If the application is determined to be greater than low or negligible risk, the rationale will be recorded and communicated back to the applicant. The study will then be referred to the HREC for review.

c) Exemption from HREC Review

i. Applications for research considered as negligible risk and involving the use of already existing data or records containing non-identifiable data may be exempt from HREC review/approval (NS 2.1.7, 5.1.22-5.1.23)\(^1\).

ii. Requests for exemption are reviewed by the QIMR Berghofer Ethics and Clinical Trials Office, and the HSSC and HREC Chairs.

d) Expedited HREC Review

All proposals must be submitted to the HREC for approval, however the HREC Chair may authorise an expedited review of research proposals between meetings. In authorising such an expedited review, the Chair may:

- Grant Executive Approval;
- Refer the application to any other member or members of the HREC, the HSSC or the CTPC for comment to assist the Chair in deciding whether approval should be given;
- Placing the request as a late item on the HREC agenda;
- Request an out of session review by HREC;
- Call a special meeting of HREC; and
- Require amendment of the proposal.

The Chair may only authorise an expedited review under this section if:

i. A deficiency in an application is identified by the HREC or additional information is required, and the HREC authorises the Chair to approve the proposal when the Chair is satisfied that the deficiency has been addressed or the additional information has been provided (an Executive Approval);

ii. There are uncontroversial amendments to an approved protocol, for example, to approve amendments requested by another HREC, to update personnel on a project, to improve trial associated procedures, or to make technical modifications to test procedures;

iii. There are minor amendments of an administrative nature, for example changes of contact details, corrections of version control and/or page numbering, or correction of minor errors in approved documents.

An Executive Approval is final and does not require further approval. All Executive Approvals will be submitted to the next meeting of the HREC for noting.

6.3 Working Procedures

Operating guidelines and working procedures relating to the committee and further detail regarding above can be found in the QIMR Berghofer HREC Administration Standard Operating Procedure document\(^4\).
7 EVALUATION OF COMMITTEE ACTIVITIES

The QIMR Berghofer HREC shall review and assess its performance annually and report the results to the Council.

A survey of members may/will include:

- Effectiveness of the induction/package for new members
- Consistency of committee business with terms of reference
- Efficiency and effectiveness of discussions and consideration of significant matters
- Skills, experience and fit of the membership
- Preparedness of members
- Clarity, sufficiency, accuracy and timeliness of agendas, papers and minutes
- Efficiency of chairing
- Ability of members to contribute and participate
- Atmosphere of meetings conducive to open and productive debate
- Conduct of members aligns with Institute values, is courteous and professional

[A survey tool can be developed for consistent use across the Institute]

8 REVIEW OF TERMS OF REFERENCE

The Committee shall review and assess the adequacy of these terms of reference every three years and, if appropriate, recommend changes to the terms of reference to the Council.

Approval of the Terms of Reference is by the Council.

9 REFERENCES


RELATED DOCUMENTS:

QIMR Berghofer Code of Conduct
QIMR Berghofer Policy on the Responsible Conduct of Research and Research Misconduct
QIMR Berghofer Clinical Trials Code of Conduct Policy

Note: Documents listed here are amended from time to time.

10 AMENDMENT HISTORY

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