HUMAN RESEARCH ETHICS COMMITTEE TERMS OF REFERENCE

APPROVED DATE: 24 October 2023
REVIEW DATE: 24 October 2026

1 BACKGROUND

1.1 The Human Research Ethics Committee (Committee) is established by QIMR Berghofer Medical Research Institute (the Institute) under the provisions of the National Statement on Ethical Conduct in Research Involving Humans (the National Statement).

2 PURPOSE

2.1 The Committee reviews and issues Institute approval for research proposals involving human participants to ensure that they are ethically acceptable and follow relevant standards and guidelines.

2.2 The Committee is registered with the National Health and Medical Research Council (NHMRC) (Registration No: EC00278), and through certification as a lead Human Research Ethics Committee (HREC) under the National Approach to Single Ethical Review of Multi-Centre Research.

2.3 The Committee is certified by the NHMRC for single ethical review of studies involving adults: specifically, 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 GOVERNANCE

3.1 The Committee is accountable to and reports to the Deputy Director & Chief Scientist and, through the Deputy Director & Chief Scientist, to the Council of the Queensland Institute of Medical Research (Council).

3.2 To ensure good communication between the Committee, Council and Management:
   a) the Committee shall submit a quarterly activity report to the Council via the Council’s Audit, Risk & Finance Committee;
   b) the Chairperson shall be invited to meet directly with the Council once per year; and
   c) the Chairperson shall be invited to meet with the Director & CEO twice per year.

3.3 In addition, the Committee Chairperson may escalate an issue or risk to the Council at any time, via the Council Secretary.

4 ROLE AND RESPONSIBILITIES

4.1 The role of the Committee is to:
   a) consider ethical implications of all proposed human research projects submitted to the Committee, that are to be conducted:
      i. within the premises of the Institute, including both the Institute and non-Institute
and determine whether to approve, request amendment of, or reject a project on ethical
grounds, based on the requirements of the National Statement;
b) monitor, review, and if necessary, suspend or withdraw approval for any research project if
the Committee is not satisfied that the conduct of research continues to conform with the
approved proposal;
c) receive and refer to the Research Integrity team complaints and issues of non-compliance
raised by any person in relation to research that has been considered and approved by the
Committee but which cannot be resolved by the Committee;
d) submit a quarterly report to the Council, via the Council’s Audit, Risk and Finance Committee
and the Deputy Director & Chief Scientist;
e) provide an annual report to the NHMRC, and any further information as requested; and
f) provide information and reports to the Therapeutic Goods Administration (TGA) where
appropriate.

4.2 Before granting approval to a human research project, the Committee must be satisfied that the
protocol conforms to:
   a) The National Statement1; and
   b) Other relevant ethical standards, Codes and guidelines;

5 MEMBERSHIP

5.1 Composition

The HREC is established in accordance with the National Statement1 with a minimum
membership of eight.

5.2 Appointment of Members

   a) The Chairperson and Deputy Chairperson are appointed by the Council, on recommendation
      of the Deputy Director & Chief Scientist.
   b) All other members are appointed by the Deputy Director & Chief Scientist.
      i. Initial appointment shall be via a merit-based recruitment process;
      ii. Reappointment shall be on the recommendation of the Chairperson.
   c) For Institute staff seeking appointment to the Committee, the recruitment process shall
      include confirmation of the support of the member’s line management to take up, or
      continue, the member’s participation on the committee.
   d) All members are appointed as individuals for their knowledge, qualities, expertise and relevant
      experience, not as representatives of any organisation, group, or opinion.

5.3 Induction

   a) All members of the Committee are provided with a formal notice of appointment and may not

_1 Section 5.1.30_
review any applications until they have completed an induction program.

b) The induction program includes:

   i. for Institute staff, completion within the last three years of the Institute’s eLearning modules for Research Integrity;
   ii. an induction session with the Chairperson or their delegate. In the case of a new Chairperson not previously a Committee member, an induction session with a suitably experienced Committee member;
   iii. attendance at a Committee meeting as an observer with no rights of debate; and
   iv. provision of and an opportunity for familiarisation with:
       • the National Statement, and
       • these Terms of Reference.

5.4 Period of Appointment

a) A Committee member is normally appointed for a three-year term.
b) Members may be appointed to two consecutive terms.
c) Members may be appointed to more than two consecutive terms with the express approval of the Deputy Director & Chief Scientist.

5.5 Chairperson and Deputy Chairperson

a) A Chairperson and Deputy Chairperson shall be appointed by the Council, for an initial term of three years. An appointment from the ranks of the Committee shall extend that member’s term by the full three-year period.
b) The Chairperson may be appointed for no more than a second three-year term.
c) In the absence of the Chairperson, the Deputy Chairperson will perform the duties of the Chairperson.
d) The Chairperson shall impartially guide the operation of the Committee, resolve conflicts of interest related to the business of the Committee and represent the Committee in any negotiations with the management of the Institute.
e) Responsibilities of the Chairperson include, but are not limited to:

   i. ensuring that the Committee operates in accordance with the principles and requirements of the National Statement, the relevant policies of the Institute and the agreed Committee procedures;
   ii. overseeing all requirements of Committee reporting and reviewing;
   iii. advising the Deputy Director & Chief Scientist regarding the level of resourcing required by the Committee, and
   iv. meeting with the Council and Director & CEO to report on the operations of the Committee and raise any issues.

5.6 Member responsibilities

a) Members shall:

   i. thoroughly prepare for meetings by reading applications, reports and documentation provided in meeting agendas;
   ii. attend scheduled meetings to deliberate on the ethical acceptability of agenda items
for approval;

iii. actively engage in informed and thorough discussion of matters before the Committee;

iv. in a timely manner complete actions assigned to them arising from matters before the Committee, and

v. complete training appropriate to the member’s position.

b) Where a member misses 3 consecutive meetings, that member should provide a reason for missing the previous meetings to the Chairperson, who can decide whether that member should remain a member of the Committee and make recommendation to the Deputy Director & Chief Scientist.

5.7 Remuneration

a) The Council has determined to remunerate members of the Committee who are not Institute staff. Remuneration arrangements are set out in the Institute’s Remuneration of Committee Members Procedure.

b) Members employed by the Institute provide their services on a voluntary basis.

c) All essential and necessary expenses incurred by members in carrying out their Committee duties will be reimbursed by the Institute, on production of original receipts.

d) Parking will be provided at Herston for members who are not Institute employees, while attending to Committee business.

5.8 Rights of audience and debate

a) The following position holders have right of audience and debate at Committee meetings:

i. Committee secretariat;

ii. Deputy Director & Chief Scientist;

iii. General Manager, Research Governance & Funding;

iv. Any other person with the approval of the Chairperson.

b) Persons with rights of audience and debate have no decision-making authority in relation to the business of the Committee, and shall not be present during decision making or deliberation without the Chairperson’s approval.

c) Persons with rights of audience and debate are not required to be inducted to the Committee but are bound by the conflict of interest and confidentially provisions that apply to all members.

6 MEETINGS

6.1 Quorum

A quorum will comprise at least the minimum membership of eight as described in the National Statement. Where a quorum is not present, the requirements of the National Statement with regard to decision-making will be followed.

6.2 Meetings

a) The Committee will meet at least nine times per year.

b) A schedule of Committee meeting dates and agenda closing dates will be made available by the beginning of each year.
c) Extraordinary meetings of the Committee may be convened during peak workload or to review urgent committee business.

d) Meetings by Flying Minute are permissible at the discretion of the Chairperson. Such meetings would normally be reserved for urgent but uncomplicated decision making where it is not anticipated that extensive panel discussion and debate will be required. In these cases, proposals and other items of business will be circulated to the Committee members who shall consider them and, in writing, provide comments on applications or other matters of business.

6.3 Secretariat

a) The Committee is supported by the HREC Secretary, who is an employee of the Institute.

b) The HREC Secretary will:

i. In consultation with the Chairperson, prepare and send notices of meetings and agendas and accurately record all decisions of the Committee.

ii. Table all correspondence, reports, submission and other information relevant to the Committee.

iii. Organise and administer the Committee and any subcommittees.

iv. Act as a liaison between the Committee, any subcommittees and researchers.

v. Provide advice to researchers on the Institute’s process for ethics review.

6.4 Procedures

a) The HREC will operate in a manner consistent with that specified in the Institute’s HREC procedures.

7 CONFLICTS OF INTEREST

7.1 Members are required to declare any interests that could constitute an actual, perceived or potential conflict of interest in relation to their participation on the Committee, in line with the Institute’s Conflict of Interest Policy.

7.2 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.

7.3 The Chairperson will determine if members with a conflict of interest on an agenda item may remain present for the discussion of the item but not take part in a decision, or if the member must withdraw from the meeting for the discussion of matters that relate to that conflict of interest. Once such members have withdrawn, the remaining members must still constitute a quorum.

7.4 If the member with a conflict of interest is the Chairperson, the Deputy Chairperson will make the determination in paragraph 7.3.

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2 Standard Operating Procedures for Administration of the QIMR Berghofer HREC:
8 CONFIDENTIALITY

8.1 Confidential matters relating to the Committee include, but are not limited to:
   a) the content and nature of applications before the Committee;
   b) the deliberations of members during consideration of meeting business;
   c) the private information of persons internal and external to the Institute contained within
      meeting papers;
   d) arrangements involving third parties; and
   e) information relating to complaints, misconduct or investigations.

8.2 Agenda items considered during a meeting and records of specific meeting discussions may be
   shared by the Chairperson, or by the General Manager, Research Governance & Funding, with
   staff of the Institute who can demonstrate a need to access the relevant information for the
   performance of their duties.

9 SUBCOMMITTEES

9.1 Human Scientific Subcommittee
   a) The HREC is assisted by the Human Scientific Subcommittee (HSSC) which provides advice on
      scientific aspects of human research protocols and on compliance with regulatory
      requirements. The HSSC provides advice to the HREC.
   b) The HSSC is appointed by the Deputy Director & Chief Scientist of the Institute. The HSSC will
      have a Chairperson who may be a member of the HREC.
   c) The HSSC does not make decisions about the ethical acceptability of applications.

10 OTHER RELEVANT COMMITTEES

10.1 Clinical Trial Protocol Committee
   a) The Institute has established the Clinical Trial Protocol Committee (CTPC), which provides
      advice to the HREC via the Institute on the safety, feasibility and scientific acceptability of
      clinical trial proposals. The CTPC can provide written advice to the Secretariat on a clinical trial
      protocol and investigator brochure, which can then be provided to the HREC.
   b) Members of the CTPC will be engaged and remunerated by the Institute.
   c) The CTPC will report to the General Manager, Research Governance and Funding or their
      delegate.
   d) The CTPC has its own Terms of Reference.

11 REVIEW OF TERMS OF REFERENCE

11.1 Variations to the Terms of Reference of the Committee must be approved by the Council.

11.2 The Committee will review and assess the adequacy of these terms of reference at a minimum of
   every three years, and recommend any changes to the Council via the Audit, Risk & Finance
   Committee.
13 REFERENCES

National Statement on Ethical Conduct in Research Involving Humans

Conflict of Interest Policy

Remuneration of Committee Members Procedure

Standard Operating Procedures (SOPs) for Administration of the QIMR Berghofer Human Research Ethics Committee (HREC)

14 AMENDMENT HISTORY

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