1.1 Scope of Responsibilities

1.1.1 The QIMR Berghofer Medical Research Institute-Human Research Ethics Committee (QIMR Berghofer-HREC) is a committee established by the Council of the Queensland Institute of Medical Research (Council), to ensure maintenance of ethical standards in research and compliance with regulatory guidelines. QIMR Berghofer-HREC reports to the Council.

1.1.2 The QIMR Berghofer-HREC is assisted by the Human Scientific Sub-Committee (QIMR Berghofer-HSSC) and the Clinical Trial Protocol Committee (QIMR Berghofer-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 QIMR Berghofer-HREC and the Director of QIMR Berghofer. Sub-committees report to the QIMR Berghofer-HREC.

1.1.4 The QIMR Berghofer-HREC shall:
   a) Advise the Council on policy requirements relating to the National Statement, and any other relevant State, Territory and Commonwealth legislation relating to human experimentation.
   b) Consider research protocols involving human experimentation carried out:
      i. Within the premises of QIMR Berghofer, including both QIMR Berghofer and non-QIMR Berghofer scientific groups;
      ii. By QIMR Berghofer personnel, whether intra- or extra-mural;
      iii. By organisations for whom QIMR Berghofer has agreed to act.
      iv. By organisations, with whom QIMR Berghofer 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, 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 QIMR Berghofer that an appropriate expert/s be commissioned to provide that advice.
   e) Ensure that, where a project involves more than one institution, the project has obtained ethical approval from each participating institution.
   f) Maintain a register of the research protocols submitted to the QIMR Berghofer-HREC.
   g) Provide information and reports to the National Health and Medical Research Council (NHMRC) and NHMRC principal committees on request.
   h) Provide information and reports to the Therapeutic Goods Administration (TGA) of the Commonwealth Department of Health and Aged Care, where appropriate.
   i) Where the conditions of a grant involve compliance with the requirements of any other regulatory agency, particularly an overseas agency, the QIMR Berghofer-HREC will endeavour to meet those requirements. Investigators should notify the QIMR Berghofer-HREC of the requirements before the grant is accepted.

1.2 Accountability
The QIMR Berghofer-HREC is accountable to the Council. The QIMR Berghofer-HREC, before granting approval to a research study involving humans, must be satisfied that the protocol conforms to:
a) The NHMRC “National Statement”\(^2\);

b) Where relevant, Integrated Addendum to ICH E6(R1): Guideline for Good Clinical Practice E6(R2) Nov 2016\(^3\);

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

d) Where relevant, overseas regulatory requirements.

1.3 Mechanisms of Reporting

Formal mechanisms of reporting include the following:

a) A summary of significant issues raised in the minutes of all QIMR Berghofer-HREC meetings is provided to the Director’s Consultative Committee (DCC) and the QIMR Berghofer Council for consideration. A copy of the minutes is available to members online via Accellion.

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

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

2.0 Composition and Membership of the QIMR Berghofer-HREC

2.1 The QIMR Berghofer-HREC Chairperson and Deputy Chairperson

a) Both the Chairperson and Deputy Chairperson of the QIMR Berghofer-HREC are appointed by the Council.

b) In the absence of the Chairperson, the Deputy Chairperson will perform the duties of the Chairperson.

c) In the absence of both the Chairperson and Deputy Chairperson, the Chairperson may appoint an Acting Chairperson.

2.2 The QIMR Berghofer-HREC Secretary

a) The QIMR Berghofer-HREC Secretary is an employee of QIMR Berghofer.

b) The Secretary assists the Chairpersons of the HREC, HSSC and CTPC, and undertakes administrative tasks of the committees under the guidance of the QIMR Berghofer Regulatory Affairs Manager.

c) His/her role is to act as a liaison between the HREC, its sub-committees and the researchers.

d) The Secretary also provides administrative advice to the researchers on the Institute’s process of ethics review.
2.3 Membership of the QIMR Berghofer-HREC

The QIMR Berghofer-HREC is established in accordance with the prescriptions set out in the National Statement (NS5.1.30) consisting of at least the minimum membership of eight as follows:

a) A Chairperson;
b) At least two lay people, one man and one woman who have no affiliation with QIMR Berghofer and do not currently engage in medical, scientific, legal or academic work;
c) A person with knowledge of, and current experience in, the professional care, counselling or treatment of people;
d) A person who performs pastoral care in a community, for an example, an Aboriginal elder, or a minister of religion;
e) A lawyer, who is not engaged to advise QIMR Berghofer; and
f) At least two people with current research experience that is relevant to research proposals considered by the QIMR Berghofer-HREC.

2.4 Appointment of Members

a) Vacancies on the committee may be advertised via publications such as QIMR Berghofer’s “LifeLab”, Queensland Health’s “Healthmatters”, UQ’s “University News”, Australian Institute of Company Directors, SEEK etc.
b) Upon submission of a Curriculum Vitae and approval by the Chairperson (which may 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 familiarise him/her-self with committee procedures and workings. Subsequent to agreement from all parties (prospective member and Chairperson), a nomination for membership is sent to the Council for consideration.
c) QIMR Berghofer-HREC members are appointed by the Council. All changes to the membership are communicated to the NHMRC, AHEC, and other official research regulatory bodies as required.

2.5 Period of Appointment

a) QIMR Berghofer-HREC members are normally appointed for a three-year term.
b) A retiring member may be re-appointed. Appointments to fill casual vacancies are for the balance of the original appointee’s term.
c) Appointment may be terminated by either party after two months’ notice given in writing.

2.6 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 QIMR Berghofer-HREC and any requirements for confidentiality, privacy and training/professional development required by QIMR Berghofer.
c) Members receive a formal notice of appointment and assurances that they will be covered by QIMR Berghofer insurance policies as they relate to professional indemnity whilst performing the business of QIMR Berghofer-HREC.
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.

2.7 Remuneration

a) All essential and necessary expenses incurred by members in carrying out their QIMR Berghofer-HREC duties will be reimbursed by QIMR Berghofer, on production of original receipts.
b) Internet access may be provided to the primary place of residence to members who are not staff of the QIMR Berghofer or co-located entities to enable review of electronic research protocols.
c) Parking will be provided at Herston for members, who are not QIMR Berghofer employees, while attending to QIMR Berghofer-HREC business.

3.0 Written Proposals

a) The QIMR Berghofer-HREC requires project applications to be submitted via the QIMR Berghofer Electronic Form system for human ethics approvals.
b) Human experimentation proposals (non-clinical trial) must conform to the requirements of the ‘National Statement’² and researchers must provide sufficient information required for scientific and ethical evaluation of the protocols.
c) In addition to the ‘National Statement’², Clinical trials protocols must conform also to the requirements of the ‘Integrated Addendum to ICH E6 (R1): Guideline for Good
Clinical Practice E6(R2) Nov 2016 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 is recorded and available for review in the QIMR Berghofer Electronic Form system.

4.0 Alternate Review Pathways

4.1 Minimising duplication of ethical review

a) A waiver from ethical review may be applicable to projects in which QIMR Berghofer-HREC is not the lead approving committee, and ethical review and oversight of the project is provided by another NHMRC-accredited HREC (NS5.3).

b) Submissions for a waiver must be accompanied by evidence that the other HREC has reviewed and approved the nature of the work occurring at QIMR Berghofer. 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 MTA may still be required.

c) Applications for a waiver will be considered by the QIMR Council Delegate. The Council Delegate may request additional information or refuse a waiver if deemed unsuitable.

d) QIMR Berghofer sponsored studies are not eligible for a waiver from QIMR Berghofer-HREC review.

4.2 Low and Negligible Risk Research Protocols

a) Applications for research that carry no more than low or negligible risk may be submitted for review to a scientific sub-committee of the HREC, or other HREC Delegate (NS5.1.18 - 5.1.21).

b) Applications determined to fit the definition of low or negligible research as defined in the National Statement (NS2.1.6 – 2.1.7), may be approved by the HREC Delegate or scientific sub-committee without being reviewed by the HREC.

c) 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.

4.4 Exemption from HREC Review

a) Applications for research that is considered negligible risk and involve 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)

b) Requests for exemption are reviewed by the QIMR Berghofer Regulatory Affairs Office.
4.5 Expedited HREC Review

Although in general, all proposals must be submitted to the QIMR Berghofer-HREC for approval, the QIMR Berghofer-HREC has provision for expedited review of research proposals between meetings. Executive approval process may be used in the following circumstances:

a) Where a deficiency is identified by the QIMR Berghofer-HREC or additional information is required, the QIMR Berghofer-HREC may authorise the Chairperson or Delegate to approve the proposal executively when the Chairperson or Delegate is satisfied that the deficiency has been addressed or the additional information has been provided.

b) Executive approval may be requested by the researcher to expedite approval of non-controversial 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.

c) Executive approval may be requested to expedite approval of minor amendments of administrative nature, for example changes of contact details, corrections of version control and/or page numbering, or correction of minor errors in approved documents.

d) Executive approval process is unlikely to be appropriate for a new protocol unless there is mutual acceptance agreement in place.

e) Requests for executive approval may be made through the Secretary to the Chairperson or any HREC Member, delegated to act as HREC Chairperson (the Delegate).

f) If the Chairperson (or Delegate) is satisfied that the submission meets the requirements for Expedited Approval/Executive Approval, the Chairperson (or Delegate) may:

   i. Grant Executive Approval.
   
   ii. Refer the application to any other member or members of the QIMR Berghofer-HREC, the QIMR Berghofer-HSSC or the QIMR Berghofer-CTPC for comment to assist the Chairperson (or Delegate) in deciding whether approval should be given.
   
   iii. Bypass the normal HREC review process by placing the request as a late item on the HREC agenda.
   
   iv. Request an out of session review by HREC.
   
   v. Call a special meeting of HREC.
   
   vi. Require amendment of the proposal.
   
   vii. Refuse the request for executive approval.

g) An executive approval is final and does not require further approval. All executive approvals will be submitted to the next meeting of the QIMR Berghofer-HREC for noting.
5.0 Working Procedures

Operating guidelines and working procedures relating to the committee and further detail regarding above can be found in the HRES SOP document.
Bibliography


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