



NHMRC National Scientific Committees

hosted by Bellberry Limited

National Scientific Committee for Complex Genetic Research

Terms of Reference

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Australian Government

National Health and Medical Research Council



Bellberry Limited

supporting research and ethics

BACKGROUND

The National Health and Medical Research Council (NHMRC) is Australia's peak body for supporting health and medical research; for developing health advice for the Australian community, health professionals and governments; and for providing advice on ethical behaviour in health care and in the conduct of health and medical research. As part of its work to support a nationally consistent approach to the way human research (including clinical trials) is conducted and overseen, NHMRC is piloting National Scientific Committees to provide advice to Human Research Ethics Committees (HRECs), sponsors and researchers on complex genetic research and clinical trials involving medical devices.

The National Scientific Committees will provide advice to HRECs, sponsors and researchers on the scientific merit and integrity of a research protocol. The committees will not provide ethics approval for human research and positive advice from a committee does not constitute an approval to commence a research project.

Under this pilot, Bellberry Limited (Bellberry), a private not-for-profit company based in South Australia, will provide secretariat and administrative support to the committees established to conduct scientific reviews of applications for complex genetic research and clinical trials involving medical devices including handling applications for review. NHMRC has provided funding to Bellberry to cover the costs associated with the pilot committees.

While the Terms of Reference, Standard Operating Procedures and the membership of the committees have been approved by NHMRC, Bellberry will be responsible for the day-to-day management of the committees.

For further information about the National Scientific Committees please see:
<http://www.nationalscientificcommittees.org.au/>

PURPOSE

This document describes the Terms of Reference for the National Scientific Committee for complex genetic research (the Committee).

1 OBJECTIVES

- 1.1 The Committee will provide independent, robust and timely expert review of the scientific merit and integrity of complex genetic research proposals.
- 1.2 Based on the review conducted, the Committee will provide advice to the applicant to assist them in addressing the ethical issues arising from complex genetic research proposals. The NSC will provide an opinion on the scientific and technical merit of the application, to be used to support the HREC review.

2 FUNCTION

- 2.1 The Committee will assess studies submitted to it and provide advice to the applicant on the research merit and integrity of the research proposal, including the scientific rationale of the proposal, the appropriateness of the research protocol and representations regarding risk and benefit.
- 2.2 The NSC will review the sufficiency of the experimental plan and identify shortcomings. It is the responsibility of the Investigator to resolve any issues identified.

3 SCOPE OF RESPONSIBILITY

- 3.1 The Committee will provide advice to HRECs, sponsors and researchers on the scientific merit and integrity of a research proposal.
- 3.2 The Committee will not provide ethics approval for research proposals.
- 3.3 The Committee will review research proposals determined by Bellberry to be eligible for review by the Committee, in accordance with these Terms of Reference.
- 3.4 Through Bellberry, the Committee will accept applications and referrals from sponsors, researchers and HRECs.

4 ACCOUNTABILITY

- 4.1 The Committee will be under the day-to-day management of Bellberry, and will be accountable to the Chief Executive Officer (CEO) of Bellberry or their delegate.
- 4.2 The Committee will adhere to the requirements of relevant written policies and procedures as developed by Bellberry.
- 4.3 The Chair of the Committee may bring issues of concern to the CEO of

Bellberry or their delegate.

- 4.4 In its capacity as host organisation, Bellberry will:
- (a) Provide NHMRC with reports on the meetings of the Committee (including attendance records) and other progress reports as required;
 - (b) make available to NHMRC for audit purposes, Minutes of Committee meetings and records of attendance;
 - (c) Publish the Terms of Reference, Standard Operating Procedures and Committee membership at (TBC);
 - (d) Provide information on matters relating to the day to day operation of the committee via website and an appointed contact, including:
 - i. the lodgement and review process;
 - ii. the review status of a proposal;
 - iii. how to respond to questions from the Committee;
 - iv. the day-to-day management of the Committee;
 - v. the expertise of the Committee members; and
 - vi. Bellberry generally.
- 4.5 NHMRC will provide information on matters relating to the National Scientific Committee pilot generally, including:
- (a) questions regarding the relationship between the reviews and advice provided by the Committee and review by HRECs; and
 - (b) questions and comments regarding NHMRC's relationship with Bellberry.

5 COMPOSITION AND SELECTION OF THE COMMITTEE

- 5.1 The Committee will be drawn from a Panel of eligible members. The Panel will comprise a minimum of eight members with experience in:
- (a) Human genetic research;
 - (b) Clinical research;
 - (c) Good Clinical Practice and TGA Requirements for biologicals; and
 - (d) The review and assessment of human research protocols.
- 5.2 In consultation with NHMRC, the Bellberry CEO will ensure that a Chairperson is appointed to the Committee with suitable experience in one of the above areas identified in 5.1, and whose other responsibilities will not impair their ability to oversee the operations of Committee meetings.
- 5.3 The Chairperson should not be the Chair of a HREC to which the advice from the Committee will be provided, if known.

- 5.4 Potential Panel members will be identified and nominated by the Bellberry CEO for consideration by NHMRC.
- 5.5 Members must hold appropriate qualifications and be recognised in their field as possessing expertise in human genetic research, for example a Fellowship in a relevant professional college, or a senior academic position (Level D or E).
- 5.6 NHMRC will approve or decline to approve nominated Panel members, based on their expertise in human genetic research.
- 5.7 NHMRC-approved Panel members will be officially appointed by the Bellberry CEO.
- 5.8 Subject to NHMRC approval, members may be added to the Panel at any time.
- 5.9 Bellberry will select a Chairperson and at least three Panel members to make up a Committee for each meeting. Members will be selected based on:
 - (a) ensuring that appropriate expertise is available for the review of each proposal;
 - (b) enabling the timely review of all studies;
 - (c) the availability of individual members of the Panel;
 - (d) assessment of any interests disclosed; and
 - (e) any relevant advice provided by the Chairperson.

6 MEETINGS

- 6.1 A quorum for a meeting will be a Chairperson and three members of the Committee.
- 6.2 At the meeting, the Chairperson will seek any further disclosures of interests not previously advised from Committee members and advise on how those interests will be managed.
- 6.3 The Committee may review one or more research proposals at any meeting.
- 6.4 NHMRC or Bellberry representatives may attend a Committee meeting in an ex officio capacity, subject to confidentiality agreements being in place.
- 6.5 Meetings may be held physically, or in alternative format such as by video or teleconferences. Where possible, all members should be present at the meeting. However, where absence is unavoidable, the chairperson should be satisfied, before a decision is reached etc. (5.2.30.)

7 MEMBER REMUNERATION

- 7.1 Committee members are remunerated in accordance with a schedule developed by Bellberry, in consultation with NHMRC, and this schedule will be published online.

8 OTHER MATTERS

- 8.1 Committee members who review a research proposal may be able to take part in a subsequent HREC review of the same proposal, provided they disclose their involvement in the prior review of the proposal and the HREC Chairperson agrees.