

# The Royal Australian College of General Practitioners

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| <b>1.</b>  | <b>POLICY TITLE</b>       | <b>RACGP National Research and Evaluation Ethics Committee (NREEC) – TERMS OF REFERENCE</b> |
| <b>1.1</b> | <b>Policy Number:</b>     | <b>CO-O-018.0</b>   |
| <b>1.2</b> | <b>Category:</b>          | <b>Organisational</b>   |
| <b>1.3</b> | <b>Approval Date:</b>     | <b>9 August 2021</b>  |
| <b>1.4</b> | <b>Revision Due Date:</b> | <b>9 August 2024</b>  |
| <b>1.5</b> | <b>Unit Responsible:</b>  | <b>Research Unit</b>  |

## **2.0 POLICY DECLARATION**

- 2.1 The RACGP Constitution empowers the Board, by clause 90, to establish one or more committees of such member or members of the College as the Board thinks fit. Any committee so formed must conform to any regulations imposed by the Board. The advice and assistance provided to the Board by its committees vitally assists the College's mission. The importance of the matters dealt with by such committees, reflected in the requirements of clause 90 of the Constitution, means that a clear Terms of Reference document is required to ensure appropriate governance and effectiveness.
- 2.2 The following provisions set out clearly the terms of establishment of the National Research and Evaluation Ethics Committee (NREEC), its membership, responsibilities and proceedings, save and except only to the extent otherwise specifically regulated in any particular instance.

## **3. AUTHORITY**

- 3.1 This document has the force of a Regulation made by the Board in accordance with clause 70(b)(v) of the Constitution and replaces all prior Regulations dealing with the same subject matter, other than those contained within the Faculty Regulations and the Standing Orders.

## **4. ESTABLISHMENT**

- 4.1 The NREEC is established as a Human Research Ethics Committee under the guidelines set out in the *National Statement on Ethical Conduct in Human Research 2007 (updated 2018)* developed jointly by the National Health and Medical Research Council, Australian Research Council, and Australian Vice-Chancellors' Committee (the '*National Statement*').
- 4.2 These terms of reference are to be read in conjunction with Section 5 of the *National Statement* which sets out the processes of research governance and ethical review, with which the NREEC is compliant.
- 4.3 The NREEC is a sub-committee of the RACGP Expert Committee – Research (REC-R) and it shall in the first instance report to the Chair, REC-R, and then to the RACGP Board via the Chief Executive Officer.
- 4.4 The NREEC is established with the purpose of assessing the ethical principles and associated guidelines for research involving humans in the Australian primary care setting, and to protect the welfare and rights of the research participants. The committee shall also facilitate research that is or will be of benefit to the researcher's community or to humankind.

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## 5. MEMBERSHIP

### 5.1 Members

- 5.1.1 The composition of the NREEC shall be consistent with the requirements of the *National Statement* and shall comprise no less than eight members. As far as possible there should be equal numbers of men and women.
- 5.1.2 Membership shall include:
- (a) the Chairperson, with suitable experience, whose other responsibilities will not impair the NREEC'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 RACGP 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, or 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. These people will usually be general practitioners in current practice.
- 5.1.3 No member may be appointed in more than one of the categories listed in paragraph 5.1.2.
- 5.1.4 Additional members, as deemed necessary by the Chair and approved by the Board, may be appointed as necessary.
- 5.1.5 Wherever possible four or more of the members should be experienced in reflecting on and analysing ethical decision making.
- 5.1.6 A Deputy Chair shall be appointed from the NREEC membership.
- 5.1.7 A designated RACGP Ethics Officer will be in attendance.

### 5.2 Term of Appointment

- 5.2.1 Members will be appointed for a term of three years. The Board may renew the appointment of members for a further term.

### 5.3 Processes for Appointment

- 5.3.1 Members shall be appointed to the NREEC using open and transparent processes.
- 5.3.2 Members shall be appointed as individuals for their knowledge, qualities and experience, and not as representatives of any organisation, group or opinion.
- 5.3.3 The RACGP Board shall endorse all appointments to the NREEC.

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5.3.4 Members shall be provided with a formal notice of appointment. Members shall sign and return to the CEO or the CEO's nominee a duly completed acceptance of appointment in the form approved by the CEO.

## 5.4 Conduct

5.4.1 Every member of the NREEC shall comply at all times with the **RACGP member Code of Conduct**.

## 5.5 Remuneration

5.5.1 Committee members shall be entitled to receive:

- (a) reimbursement of any travel, accommodation or other incidental expenses incurred with the prior approval of the relevant RACGP General Manager or their delegate, in accordance with the RACGP Travel and Hospitality Policy; and
- (b) payment in accordance with their relevant member service or consultancy agreement. The RACGP must ensure members are aware, such as by its inclusion in the relevant service or consultancy agreement, it does not retain any pay as you go withholding tax or superannuation guarantee contributions from fees paid.

## 5.6 Indemnity and Insurance

5.6.1 In accordance with the RACGP Constitution clauses 107 to 109 inclusive, and as required by the *National Statement, Legal protection for those involved in ethical review of research, section 5.1.9*, members of the NREEC and any expert advisors consulted by the NREEC for NREEC business shall be indemnified for liabilities that might arise in the course of bona fide conduct of their duties in this capacity.

## 6. PROCEEDINGS

### 6.1 Responsibilities

6.1.1 The NREEC's primary task is to assess the ethical principles and associated guidelines for research involving humans in the Australian primary care setting, and to protect the welfare and rights of the participants in research. The committee may also facilitate research that is or will be of benefit to the researcher's community or to humankind.

6.1.2 Each member of the NREEC is responsible for deciding whether, in their judgement, a proposal submitted to the NREEC meets the requirements of the *National Statement* and is ethically acceptable.

6.1.3 In carrying out its functions the NREEC shall at all times:

- (a) Operate in accordance with the *National Statement*;
- (b) Promote the advancement of knowledge by research and ensure that the rights of the subjects of research take precedence over the expected benefits to human knowledge;
- (c) Ensure that in all projects involving human subjects and relating to health, free and informed consent of the subjects is obtained, where applicable;

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- (d) Ensure that no member of the committee adjudicates on projects in which there may be personal involvement;
- (e) Ensure that projects take account of local cultural and social attitudes;
- (f) Give its own consideration to projects that involve research in more than one institution;
- (g) Require the principal investigator to disclose any previous decisions regarding the project made by another Human Research Ethics Committee (HREC) and whether the protocol is before another HREC; and
- (h) Determine the method of monitoring appropriate to each project.

## 6.1.4 In addition:

- (a) The NREEC will accept applications from all members of the primary health care community. This includes, but is not limited to, applications from members and non-members of the RACGP;
- (b) Issues of particular ethical interest are outlined in the National Statement and include, but are not limited to, participant consent, information for participants, potential risks and benefits to participants, the research value of the study to the participant and to the community, the competence of the researcher, and the adherence to the relevant legislation and regulations, including those concerning privacy and the confidentiality of data;
- (c) Projects that have received ethical approval will be monitored in order to ensure that they conform to the protocol approved. The Committee shall request that any amendments to approved protocols be presented to the Committee for approval;
- (d) The Committee's enquiries of the researcher will be made in a spirit of courtesy and support, so as to develop mutual respect and a sense of partnership in the development of sound ethical practice;
- (e) The decisions of the committee shall be provided in writing and within a reasonable timeframe to the persons nominated in the submission; and
- (f) Where the Committee had sought alterations, amendments or clarification, the Committee may resolve that the Chairperson give provisional approval after receiving notification in writing from the applicants of agreed changes to the project.

## 6.2 Conflicts of interest

- 6.2.1 Members must disclose any actual or potential conflict of interest, including any financial or other interest or affiliation that bears on any research reviewed by the NREEC.

## 6.3 Meetings

- 6.3.1 The NREEC will meet for the dispatch of business, adjourn and otherwise regulate its meetings as it thinks fit provided that:
  - (a) the NREEC shall meet every two months unless there is an insufficient number of applications for review. The Chair has the option to call additional meetings of the NREEC as required;
  - (b) meetings may, according to the needs of the business to be transacted and with approval of the Chair, be held face to face or by electronic means of

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communication allowing all persons participating in the meeting to hear each other at the same time. Any members of the NREEC participating in such a meeting shall be deemed to be personally present at the meeting;

- (c) not less than 7 days' notice (exclusive of the day on which the notice is served or deemed to be served, but inclusive of the day for which notice is given) specifying the place, the day and hour of each meeting shall be given to all members of the NREEC accompanied by an agenda of business proposed to be discussed at the meeting with all necessary documentation and reading material pertaining to the agenda items;
- (d) the CEO or the CEO's delegate shall be entitled to attend any meeting of the NREEC but shall not be counted in a quorum for the purposes of paragraph (e); and
- (e) the quorum shall consist of 50% of the voting members. As far as possible, at least one member in each category should attend each meeting. The Chair shall ensure that at least one member from each of the member categories defined by the NHMRC has had the opportunity to comment on each submission.

6.3.2 The NREEC will endeavour to reach decisions by general agreement. This need not involve unanimity.

6.3.3 All acts done by any meeting of the Committee or by any person acting as a member of the Committee shall, notwithstanding that it is afterwards discovered that there was some defect in the appointment of the person to be a member of the Committee, or to act as a member of the committee, or that a person so appointed was disqualified, be as valid as if the person had been duly appointed and was qualified to be a member of the committee.

## 6.4 Recording and Reporting

6.4.1 Any member of the Committee acting or intending to act as a spokesperson for the Committee or the College may only do so, if at all, upon the delegated authority of the RACGP President in accordance with the RACGP spokespersons policy.

6.4.2 The NREEC shall cause minutes to be made:

- (a) of the names of members of the Committee present at all meetings of the Committee; and
- (b) of all proceedings at all meetings of the Committee.

6.4.3 The NREEC shall provide to the CEO or CEO's delegate reports concerning activities and those of its members at such times and in such format as from time to time requested by the CEO.

6.4.4 The NREEC shall prepare and submit to the Board regular reports concerning its activities at the time and in the format requested by the CEO, CEO's delegate or the President. The NREEC shall also produce an annual report to the NHMRC.