



# Human Research Ethics Committee – Terms of Reference

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<b>Approved by:</b>	CEO	<b>Next Review:</b>	14/12/2019
<b>Approval date:</b>	14/12/2016	<b>Version:</b>	Current

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## **1. TITLE**

Human Research Ethics Committee

## **2. PURPOSE AND AUTHORITY**

- 2.1 The RANZCO Human Research Ethics Committee (HREC) has been established as a Committee of RANZCO, directly responsible to the Board.
- 2.2 RANZCO is responsible for ensuring compliance by the HREC with statutory requirements and RANZCO policies and procedures, and to whom the HREC reports on a routine basis.
- 2.3 In accordance with the National Statement on Ethical Conduct in Human Research, 2007, Updated 2018 (hereafter referred to as the National Statement), RANZCO undertakes to adequately resource and maintain the HREC, which is composed, and functions in accordance with the National Statement. RANZCO accepts legal responsibility for decisions and advice received from the HREC and indemnifies members of the HREC acting in good faith for the purposes of discharging the Committee's role.
- 2.4 The RANZCO Board confirms that the HREC has been registered with the *National Health & Medical Research Council – Australia Health Ethics Committee* on 25 August 2005.
- 2.5 In performing its responsibilities, the HREC is governed by the *National Statement*, relevant state and commonwealth legislation, policies and codes.

## **3. CODE OF CONDUCT**

The RANZCO's Code of Conduct (the Code) reflects RANZCO's values, the College Oath and prevailing community expectations concerning the practice of ophthalmology. The Code has been adopted by the RANZCO Board to ensure the highest standards of ophthalmic practise and care by RANZCO members. As a condition of RANZCO membership, all members must abide by the Code at all times, including when conducting activities as a member of the HREC. These Terms of Reference are RANZCO policy. To meet the Code's required Standard of Collegiality, members of the HREC must not engage in conduct that represents a serious breach of RANZCO policy. Alleged breaches of the Code shall be determined in accordance with the Code of Conduct Procedure Policy.

## 4. ROLE & RESPONSIBILITIES

- 4.1 As set out in the *National Statement* the primary role of the HREC is to protect the welfare and the rights of participants in research and the primary responsibility of each member is to decide, independently, whether the conduct of each research proposal submitted to the HREC will so protect participants.
- 4.2 The HREC, and its sub-committees, is responsible for ensuring the ethical acceptability of research conducted by RANZCO Fellows, staff, Trainees and other prospective researchers, involving human participants, human tissue or personally identifiable records, and for the provision of advice to RANZCO on related matters.
- 4.3 In meeting its responsibilities, the HREC shall;
- 4.3.1 Receive and examine applications for ethics clearance for human research projects and shall give a final decision of:
- Approved
  - Approved with comments
  - Not approved
- In reaching a decision, the HREC may take independent advice to ensure the validity of the research methodology proposed.
- 4.3.2 Provide for the monitoring of approved research projects until completion.
- 4.3.3 Suspend or withdraw approval for any project, which no longer complies with the approved research protocol or where the research ceases to be ethically acceptable.
- 4.3.4 Provide for a confidential mechanism for receiving complaints or reports on the conduct of research projects.
- 4.3.5 Maintain a register of all applications for ethics clearance, which records the history of each application/project until its finalization.
- 4.3.6 Provide when required, the membership list present on the day a given study was approved, to the sponsor representative.
- 4.3.7 Advise the RANZCO Board of any measures required to comply with the provisions of the *National Statement*.
- 4.3.8 Report annually to the RANZCO Board, the *National Health Medical Research Council* and the *Australian Health Ethics Committee*, or as otherwise required.
- 4.3.9 Perform all other duties as determined by the *National Statement*.

## 5. TERMS OF MEMBERSHIP

- 5.1 As approved by the RANZCO Board, HREC members shall be appointed having consideration to the aims and intent of the RANZCO Diversity and Inclusion Policy and RANZCO's commitment to achieving a goal of 35% female representation on all committees and leadership bodies. Individual HREC members shall have regard to the aims and intent of the RANZCO Diversity and Inclusion Policy and adopt an inclusive approach to all HREC and RANZCO-wide activities.
- 5.2 The HREC is constituted in accordance with the *National Statement* and exceeds the minimum membership as set out in the *National Statement*:
- 5.2.1 Eight (8) members, selected by the Board in consultation with the HREC, comprising:
- a chairperson, with suitable experience, whose other responsibilities will not impair the HREC's capacity to carry out its obligations under this National Statement;
  - at least two lay people, one man and one woman, who have no affiliation with the institution and do not currently engage in medical, scientific, legal or academic work;
  - at least one lawyer, where possible one who is not engaged to advise the institution;
  - at least one person who performs a pastoral care role in a community, for example, an Aboriginal elder, a minister of religion;
  - 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 expertise;
  - 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.
- 5.2.2 Such additional co-opted members as the RANZCO Board may approve upon the request of the Committee.
- 5.2.3 A RANZCO Board member may be present at Committee meetings to ensure cross communication and information flow that would assist informed decision making within RANZCO.
- 5.2.4 Members of the HREC who are not affiliated with RANZCO are reimbursed travel, parking and extraneous costs associated with

attending meetings and other business associated with their membership of the HREC. There is otherwise no remuneration to members.

- 5.3 Committee members should be required to remain in the position for a period of three years, with the option of two more terms. The position of Chair is a three-year term, renewable for two more terms. The chair shall be elected by the RANZCO Board. The President, or a delegated Director/s, are ex-officio on the HREC Committee.
- 5.4 Any vacant positions may be filled on a casual basis with consent of the committee members for the remainder of the term.
- 5.5 RANZCO Staff members within a committee do not have voting rights and may only be included in the committee on a non-voting basis.
- 5.6 Committee members shall cease to be a member of the committee if they:
  - Resign from the committee
  - Fail to attend 3 consecutive meetings
  - Breach confidentiality
  - Act in a manner this is detrimental to the interests and objectives of the committee
- 5.7 Appointment under these Terms of Reference may only be accepted by completion and return of the Appointment Acknowledgment and Agreement section on the final page

## **6. CONFLICTS OF INTEREST**

Conflicts of interest arise when an individual prioritises, or gives equal weight to, a secondary interest over a primary interest. Where conflicts of interest exist, or are perceived to exist, they undermine the credibility, reputation and efforts of the College, its committees and its work. As such, all HREC members must strictly comply with the Conflict of Interest Policy while engaged in HREC activities. All HREC members must complete the declaration form in the Policy and all HREC meetings must begin with the declaration of relevant interests and the management of any relevant conflict of interest in accordance with the Conflict of Interest Policy.

## **7. VOTING PROCEDURE**

While a unanimous decision is preferable a two thirds majority is sufficient for a valid HREC decision, as long as one lay member is included in the majority.

Minority views of two or more members should be recorded in the minutes.

## **8. MINUTES AND MEETINGS**

The Committee minutes and meeting papers should be distributed to the Chair and other members within 5 days following a meeting.

- The Committee shall meet quarterly
- The format of the Committee minutes shall be as Minutes
- The minutes of each meeting shall be prepared by the RANZCO Manager.
- The minutes of each committee meeting shall be monitored and maintained by the RANZCO Manager as a complete record as required under the provisions of the Archives Act 1983
- By agreement of the Committee, out-of-session decisions shall be deemed acceptable. Where agreed, all out-of-session decisions shall be recorded in the minutes of the next scheduled Committee meeting.

## **9. CONFIDENTIALITY**

All RANZCO HREC materials, documents, deliberations, discussions, case notes, file notes, minutes and communications, undertaken or prepared by HREC members in connection with HREC activities or disclosed to a HREC member in connection with those activities are strictly confidential (Confidential Information). Confidential Information may only be used by a HREC member for and in connection with authorised HREC activities during the term of the appointment of the member and must not be disclosed by a HREC member to a non-HREC member without express HREC approval. Where Confidential Information is to be disclosed to a non-member, such disclosure must be on agreed terms approved by the Chair and restricted to a specific purpose and specified duration. All Confidential Information held by a HREC member must be securely destroyed or returned to the HREC upon conclusion of the appointment.

## **10. UNAUTHORIZED COMMUNICATION**

Communicating about Committee matters to those outside the Committee without the express endorsement or permission of the CEO or Board is referred to as unauthorised communication. Committee members must be cognisant of their implied authority to 'speak' on behalf of the Committee or RANZCO when communicating to non-Committee members about issues pertaining to the Committee. This is because unauthorised communication may damage the reputation of RANZCO and give rise to liability on the part of the College.

When communication is necessary with stakeholders other than those normally engaged in the course of Committee activities, i.e. relevant government departments, other colleges, key stakeholder groups, the Chair of the Committee must seek approval from RANZCO's CEO before undertaking communication.

Under no circumstances shall the Committee or any of its members conduct any unauthorised communication (written or oral) concerning any proposed or current legal action or political lobbying.

All media communications (print, electronic, radio, television etc) must be coordinated by the RANZCO Manager of Communications.

Where a Committee member makes representations to the media in their personal capacity, the Committee member must take all reasonable steps to ensure that the representations are not attributed to or taken to be endorsed by RANZCO.

## **11. COMMITTEE PERFORMANCE AND REVIEW**

The Committee shall engage in reflective, self-evaluation processes to improve its effectiveness and this may involve attending a triennial course which is run either within RANZCO or as part of an external training institution.

The Committee shall undertake a planning session to reconfirm its commitments to strategic priorities identified within Terms of Reference every three years or as otherwise directed by the RANZCO Board.

A report of the key objectives and achievements of the Committee for the previous financial year is to be provided by the Chair to the RANZCO Board by 31 July each year for potential inclusion in RANZCO's Annual Report. A plan for the year ahead noting key objectives is to be provided at the same time.

The Committee Chair shall also report to the RANZCO Board by 31 July each year on the adequacy of contributions made by members.

The template reporting form is at **Attachment A**.

The Terms of Reference shall be reviewed every three years or as otherwise directed by the RANZCO Board.

**RECORD OF AMENDMENTS**

<b>Page</b>	<b>Details of Amendment</b>	<b>Date Approved</b>

## Attachment A: Annual Committee Reporting Form

Committee Title: \_\_\_\_\_ Chair: \_\_\_\_\_ Year: \_\_\_\_\_

1. Key objectives at year start:
2. Key achievements at year end:
3. Have members' contributions been adequate? List key contributions by members.
4. Further comments (e.g. underperformance by members):
5. Plan for the new year, noting key objectives:

## Annex 'A'

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### **2017 RANZCO Human Research Ethics Committee**

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Professor Mark Radford	FRANZCO (Chair) -	Signs off on approval letters
Dr Alex B. L. Hunyor	FRANZCO	
A/Prof Paul Healey	FRANZCO	
Dr Colin Clement	FRANZCO	
Dr Colin Chan	FRANZCO	
Dr Mei Hong Tan	FRANZCO	
Dr Malvika Gupta	FRANZCO	
Dr Christopher Basten	Clinical Counsellor	
Ms Kylie Lloyd	Female Lay Person	
Mr Bradley Sheehan	Male Lay Person	
Ms Rosemary MacDougal	Lawyer	
Professor Gerard Moore	Pastoral Care Representative	

## ***APPOINTMENT ACKNOWLEDGEMENT AND AGREEMENT***

To confirm your appointment under these Terms of Reference, please specify your full name, sign and date where indicated below and return.

*I, the undersigned, agree and state upon acceptance of the appointment that:*

- *I will comply with these Terms of Reference (as amended or replaced);*
- *Compliance with these Terms of Reference is a condition of my ongoing appointment;*
- *I am not subject to any perceived or real conflict of interest with the activities of the HREC at the date of appointment; and*
- *A breach of these Terms of Reference may constitute a serious breach of College Policy under the Code of Conduct.*

*Print Name:*

*Signature:*

*Date:*