

Human Research Ethical Clearance Policy

Policy Code: RES-004

Version: 6.0

Effective Date: 2 August 2022

Purpose

This policy outlines the College's position on human research activities that occur under its auspices. As an institution, the College is committed to a program of research which values ethical conduct and promotes ethically sound research. This policy requires research that is justified with regard to the four core ethical principles described by the [National Statement on Ethical Conduct in Human Research](#) (the *National Statement*) published by the National Health and Medical Research Council, the Australian Research Council and Universities Australia. These principles are:

- Merit and integrity
- Beneficence
- Justice, and
- Respect.

This policy, together with the Research Policy, aims to foster a research culture that may be of benefit to the College, to disciplines of interest and to the wider Australian community.

Definition of "College" – *The Australian College of Natural Medicine Pty Ltd (ACNM) trades as Endeavour College of Natural Health and Endeavour Wellness Clinic. For the purpose of this policy, any reference to 'College' or 'the College' should be considered a reference to each or any of these respective trading names / entities.*

Scope

- All campuses (including online) and clinics
- All staff undertaking human research
- All students
- External researchers using Endeavour resources

Policy Statement

Human research includes any research conducted with or about people, or their data or tissue. While a proportion of human research carries little risk, and the significant proportion of research in Australia has been carried out in a safe and responsible manner, the College is committed to ensuring it fulfils its ethical responsibility to individuals involved in research. All projects which involve people (including their data or tissue) must be approved by either an Australian Human Research Ethics Committee (HREC) or other non-HREC institutional ethics review body.

Research involving human participants needs to be conducted in a manner which ensures that ethical values and principles are adhered to at all times. The National Health and Medical Research Council (NHMRC) requires human research ethics review bodies to be satisfied that the core principles are addressed and reflected in the research design: that a research proposal meets the requirements of the National Statement. Researchers seeking ethics approval and conducting research under the auspices of the College are required to adhere to the principles and provisions of the *National Statement*.

An important objective of research ethics review is facilitating excellent ethical research. One component of ethical research is that the likely benefits of the research justify the risks of harm or discomfort to research participants, and to others. Risks include a potential for harm, discomfort or inconvenience. Research will be ethically justifiable only if its likely benefits justify those risks. Researchers are also obligated, in almost all projects, to obtain consent from the participants of their research and to ensure the quality of the research and appropriate dissemination of results.

Human Research Ethics Committee

The College will establish and maintain a Low-Risk Ethics Committee (LREC) to review applications for low and negligible risk projects. The *National Statement* defines low negligible risk research as:

“The expression ‘low risk research’ describes research in which the only foreseeable risk is one of discomfort. Research in which the risk for participants is more serious than discomfort is not low risk.

The expression ‘negligible risk research’ describes research in which there is no foreseeable risk of harm or discomfort; and any foreseeable risk is no more than inconvenience.” (Section 2, National Statement)

Any research deemed to be more than low risk will be referred to a NHMRC approved Human Research Ethics Committee (HREC).

The composition and operation of the Low-Risk Ethics Committee is detailed in the College’s [Academic Governance Framework](#).

Criteria for projects to be considered by the HREC or LREC

Research projects will require HREC or LREC approval if they meet one or more of the following criteria:

- The research is conducted with or about people, or their data or tissue
- The research directly or indirectly utilises College resources or facilities such as:
 - ⦿ College personnel as part of the team of investigators;
 - ⦿ Access to Endeavour Wellness Clinics, Wellnation data or internal databases (e.g. LMS);
 - ⦿ Access to students, staff and alumni or their data.

Access to College resources for research purposes

All research projects involving human participants, and which utilise College resources and facilities (either directly or indirectly), must first be approved Director of Education.

Applying for approval ethics approval

Researchers intending to undertake research involving human participants must submit an application for ethics review by approval the Low-Risk Ethics Committee.

Applications must be completed using the [Human Research Ethics Application](#) (HREA) application platform. This application must be accompanied by the LREC Risk Assessment Checklist. Any project that involves greater than low risk research must be assessed by a NHMRC approved HREC.

Any research project that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes, researchers must register the project as a clinical trial on a publicly accessible register complying with Australian standards (see information on the [Australian New](#)

[Zealand Clinical Trials Registry \(ANZCTR\) website](#)). Evidence of registration from ANZCTR must be provided with all other documentation required for ethics approval.

Following submission of the application, the research team will receive a confirmation email advising the date of the meeting at which their application will be reviewed. Applicants will receive a response from the College LREC within 7 working days of the committee meeting.

After consideration of the submission by the College LREC, the researchers will be advised of the outcome which will fall within one of four categories:

1. Accepted without revisions – work on the research project can immediately commence
2. Accepted with revisions – revisions should be resubmitted to the Committee secretariat to ensure compliance with the requests/feedback but does not require additional review
3. Referral to a HREC – where the LREC deems that the research is more than low-risk the researchers will be required to submit the work to a HREC for consideration.
4. Rejected – the proposed project is considered by the College LREC to fall outside of the principles of ethical research and is not supported.

Reciprocal Approval Ethics Approval

Applicants may apply to the College Low-Risk Ethics Committee for reciprocal approval if they have obtained approval for a research proposal from another HREC registered with the NHMRC. To apply for reciprocal approval, applicants must provide:

1. The original application to the approving/administering HREC (no new HREA application required)
2. The approval letter from the approving/administering HREC
3. Any amendments approved by the approving/administering HREC
4. Any other correspondence, including previous progress reports
5. A completed Reciprocal Approval Cover Sheet.

Applications for reciprocal approval ethics approval will be reviewed by the LREC Chairperson. Applicants will receive a response within seven (7) working days of the decision on their application.

Research Exempted from Ethics Approval

Research which involves use of collections of non-identifiable data and involves negligible risk research is usually exempt from review. Non-identifiable data in this context refers to data *“which have never been labelled with individual identifiers or from which identifiers have been permanently removed, and by means of which no specific individual can be identified. A subset of non-identifiable data are those that can be linked with other data so it can be known that they are about the same data subject, although the person’s identity remains unknown”* ([NHMRC](#))

Exemption from ethical review is not exemption from ethical behaviour. Researchers undertaking such research projects are required to complete an [Exemption from Ethics Review Form](#) to confirm the project is eligible for exemption. The application form will need to be submitted with a letter or other evidence of approval from the custodian of the data to the Director of Education. Projects involving data owned by the College must follow the Expression of Interest process outlined in the [Research Policy](#). Letters of Support from external data custodians must confirm that the access has been granted, to whom and for what purpose, and outline the original purpose of the data collection and what conditions or consent were required for its use.

Retrospective Ethics Approval

Retrospective ethics approval refers specifically to applications for ethics approval for research projects which have already commenced. Researchers must gain ethics approval from ALL relevant approvals **prior** to project commencement. Endeavour's LREC **will not** grant retrospective approval ethics approval as it contravenes the requirements of the *National Statement*.

Duration of Approval ethics approval

The Chair of the Low-Risk Ethics Committee will notify the applicant of ethics approval only when all requested information, clarification or modification have been approved. Notification of ethics approval will be granted in writing to the Chief Investigator of the research proposal. All approved research proposals will be granted approval ethics approval for three years. Should an approved research proposal not commence within the three years of approval ethics approval, the project will have its approval ethics approval revoked.

Rejection of Ethics Application

The Low-Risk Ethics Committee reserves all rights to reject a research proposal application, should the Committee deem that it does not meet the requirements of the *National Statement* and/or College policy. The LREC must state clearly the rationale for rejection and provide the researcher with recommendations for amendment. It will be the responsibility of the Chair of the LREC to ensure that all rationale for rejection is directed to the Chief Investigator.

If an application is rejected, the researcher may resubmit the application for full review after the concerns raised by the Committee have been met. If the application was rejected as the research was deemed to be more than low-risk, the researcher can seek approval via a NHMRC registered HREC.

Research ethics implications of student work

Any human research work conducted by a student at the College must be reviewed, in the first instance, by the Low-Risk Ethics Committee.

Assessment tasks which incorporate research activities involving human participants (e.g. case studies, observation activities etc.) can be reviewed through one application submitted by the subject co-ordinator or other designated person with an extended project completion period. LREC applications for such assessments must include the directions, guidelines and scope of the task as given to students to indicate how the ethical implications for human participants will be managed.

Assessment tasks which include individual research activities developed by each student must be reviewed by the College LREC as separate, stand-alone projects and comply with all aspects of this policy.

Definitions

Beneficence – Doing good for others; here also includes non-maleficence, avoiding doing harm.

High risk research – where the risk is more serious than discomfort.

Integrity – Honesty and probity as qualities of character and behaviour.

Justice – Regard for the human sameness shared by all human beings, expressed in a concern for fairness, or equity.

Low risk research / Research involving no greater than a low risk of harm – Where the risk, even if unlikely, is no more serious than discomfort.

Negligible risk research – where there is no foreseeable risk of harm or discomfort; and any foreseeable risk is not more than inconvenience.

Respect – Recognition that each human being has value in himself or herself.

Student – is an individual person who is formally enrolled to study at the College. The individual person is the person who appears on the College's documents such as enrolment, admission and payment documents, and who is assigned an individual student ID.

Related Procedures

Nil

Further Information

Related Policies

[Research Policy](#)

Related Documents

[Academic Governance Framework](#)

[Exemption from Ethics Review Form](#)

[Expression of Interest for Internal Research Program](#)

[LREC Amendment Application Form](#)

[LREC Annual Report Form](#)

[LREC Complaints Report Form](#)

[LREC Final Report Form](#)

[LREC Reciprocal Approval Cover Sheet](#)

[LREC Review Checklist](#)

[Low Risk Participant Information Sheet](#)

Guidelines

[Australian Code for the Responsible Conduct of Research \(2018\)](#)

[Guidelines approved under Section 95A of the Privacy Act 1988](#)

[Guidelines under Section 95 of the Privacy Act 1988](#)

[International Charter for Ethical Research Involving Children](#)

[National Statement on Ethical Conduct in Human Research \(2007 updated 2018\)](#)

[The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research](#)

[Understanding Consent in Research Involving Children: The ethical issues](#)

[Ethical conduct in research with Aboriginal and Torres Strait Islander Peoples and communities](#)

Benchmarking

Australian Catholic University

Australian Research Council

Deakin University

Monash University

National Health and Medical Research Council

University of Sydney

Supporting Research and Analysis

[Australian Code for the Responsible Conduct of Research 2018](#)

[Australian New Zealand Clinical Trials Registry \(ANZCTR\) website](#)

[Human Research Ethics Application](#)

Related Legislation

[National Health and Medical Research Council Act 1992](#)

Review and Approval

Policy Author

Director of Education

Policy Owner

Director of Education

Contact

Director of Education

Jenny.wilkinson@endeavour.edu.au

Recommending Body

Academic Leadership Team

Meeting date: July 2022

Approval Body

Academic Council

Meeting date: 29 July 2022

Policy Status

Revised

Responsibilities for Implementation

- Director of Education
- Heads of Department
- Low-Risk Ethics Committee

Key Stakeholders

- All staff conducting human research
- Education Board
- External researchers
- Students