

Human Research Ethical Clearance Policy

Policy Code: RES-004 **Version:** 1.0 **Effective Date:** 13 August 2015

Purpose:

This policy outlines the College's position on human research activities associated with the institution. As an institution the College is committed to a program of research which values ethical conduct and promote ethically good research. This policy requires that participants be accorded the respect and protection that is due to them. It also involves the fostering of research that is of benefit to the community.

Definition of "College" – *The Australian College of Natural Medicine Pty Ltd (ACNM) trades as Endeavour College of Natural Health, College of Natural Beauty, FIAFitnation and Wellnation. 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.*

- Scope:**
- All campuses and clinics
 - All academic staff
 - All students
 - All clinical staff
 - External researchers

Policy Statement:

Research involving human subjects needs to be conducted in a manner which ensures that ethical considerations are a fundamental component of the work. Human research includes any research conducted with or about people, or their data or tissue. Whilst most human research carries little risk, and the vast majority 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. As such all human research supported by or affiliated with the College must be reviewed and approved by the College's Human Research Ethics Committee (HREC).

Ethical clearance for human research is needed to ensure the research is relevant and that participant privacy and confidentiality is respected. Researchers are also obligated to obtain informed 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 HREC composition and functions follows the guidelines outlined in the *National Statement on Ethical Conduct in Human Research* published by the National Health and Medical Research Council and Australian Research Council for the Australian Government.

Executive Committee for the HREC

In line with *Subclause 5.1.20d of the National Statement on Ethical Conduct in Human Research*, the College may choose to appoint an Executive Committee for the HREC. The Executive Committee streamlines the human ethics process and increases the efficiency of the HREC by reducing the workload on the HREC. This allows additional time for discussion of ethical considerations, invitations to researchers and continuing education. The Executive Committee considers: modifications to research proposals defined as low risk ethical applications.

Criteria for projects to be considered by HREC

Research projects need only be considered by the HREC if they meet 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 Wellnation clinics, internal databases, students, staff and alumni;
 - or
 - Funding by the College through a grant program or other allocated funding

All research projects involving human subjects and which utilise College resources and facilities (either directly or indirectly) must first be approved by the Research Management Committee as being worthy of research merit prior to submission to the HREC.

Applying for ethical clearance

Researchers intending to undertake research involving human subjects must without exception submit an application for ethical clearance with the HREC. Applications must be completed using the National Ethics Application Form (NEAF) (available at <https://www.neaf.gov.au/>). The completed form must then be submitted via email to the Office of Research (research@endeavour.edu.au). The Office of Research will then review

the submission to ensure adequate research rigour before recommending the application to the College HREC on behalf of the research team. All projects deemed not to meet the required level of research rigour will be returned to the research team without HREC consideration.

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 HREC within seven working days of the HREC meeting.

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

1. Accepted without revisions - work on the research project can commence
2. Accepted with minor revisions – revisions should be resubmitted to the Office of Research to ensure compliance with HREC requests but does not require additional review by HREC
3. Accepted with major revision requiring additional HREC review – researchers are required to amend their proposed project to accommodate ethical concerns raised by HREC. A revised ethics application must be submitted to the College HREC for further consideration.
4. Rejected – the proposed project is considered by the College HREC to fall outside of the principles of ethical research and is not supported.

Expedited and Full Review Process

Research involving children, vulnerable groups, invasive procedures or a sensitive topic must be reviewed by a meeting of a full HREC. Low risk research may be eligible for expedited review.

In line with the National Statement on Ethical Conduct in Human Research, research is **not** low risk if it involves:

- A focus on illegal activity or highly likely to discover illegal activity
- Access to personally identifiable information/records without specific consent from the individuals to whom the information/records relate (either in the course of identifying/selecting people for recruitment or during data collection)
- A focus on Aboriginal and Torres Strait Islander peoples, groups, communities or issues

- A focus on women who are pregnant, and/or research involving the human foetus
- An innovation or intervention which is not standard practice in the study population
- A focus on people with a cognitive impairment, an intellectual disability, or a mental illness
- People highly dependent on medical care who may be unable to give consent (e.g. unconscious or too ill)
- Access to human tissue samples without specific consent from the individuals from whom the tissue was collected (this includes cell lines other than those acquired commercially)
- Human genetic studies
- Human stem cells
- Use of drugs; alternative/complementary therapies or care; or surgical or other therapeutic or diagnostic procedures and devices
- Exposing participants to ionising radiation

Applications for expedited review for ethical clearance will be reviewed by the full HREC, or where it has been appointed, the Executive Committee of the HREC. Applicants will receive a response from the Research Ethics Administration Officer within seven working days of outcome of their application being decided.

Review of approved projects follows the process outline outlined in the National Statement on Ethical Conduct in Human Research including regular updates on the progress of approved trials, mandatory annual reporting, and reporting of project variations.

Reciprocal Ethical Clearance

Applicants may apply to the College HREC for reciprocal approval if they have obtained approval for a protocol from another HREC. To apply for reciprocal approval, applicants must provide:

1. The original application to the approving/administering HREC (no new NEAF 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 HREC Reciprocal Approval Cover Sheet

Applications for reciprocal ethical clearance will be reviewed by the full HREC, where it has been appointed, the Executive Committee of the HREC. Applicants will receive a response Research Ethics Administration Officer within seven working days of outcome of their application being decided.

Negligible risk ethical clearance

Research which involves only existing collection of non-identifiable data is usually eligible for exemption from review. Exemption from ethical review is not exemption from ethical behaviour. Researchers undertaking negligible risk 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 Human Research Ethics Administration Office. 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. Projects identified as negligible risk will be reported to the HREC annually and at any other time requested by the HREC.

Retrospective Ethical Clearance

Retrospective ethical clearance refers specifically to applications for ethical clearance for research projects which have already commenced. Researchers must gain ethical clearance from ALL relevant HRECs prior to project commencement. Endeavour's HREC will not grant retrospective ethical clearance as it contravenes the requirements of the National Statement on Ethical Conduct in Research.

Ethical implications of student work

Any work conducted by a student of the College must be reviewed by the HREC. Assessment tasks which incorporate research activities involving human subjects (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. HREC 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 HREC as separate, stand-alone projects and comply with all aspects of this HREC policy.

Related Procedures:

Not applicable

Further Information:

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

Related Policies: [Research Policy](#)
[Office of Research Funding Policy](#)

Benchmarking: Monash University
National Health and Medical Research Council
Australian Research Council
Deakin University
University of Sydney

Supporting Research and Analysis: Australian code for the responsible conduct of research

Related Documents: [Academic Governance Framework](#)
[Research Strategy FY2013 - 2015](#)

Related Legislation: National Health and Medical Research Council Act 1992

Guidelines: National Statement on Ethical Conduct in Human Research

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Key Stakeholders:	<ul style="list-style-type: none"> • Associate Director – Research • All Research Staff • All Academic Staff • External Researchers • Students