
Human Research Ethical Clearance Policy

Policy Code: RES-004 **Version:** 3.0 **Effective Date:** 22 August 2014

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 promotes ethically sound research. This Policy requires research that balances potential risks and harms against the potential value of rigorous research. It 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, 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 (including online) and clinics
 - All academic staff and contract academics
 - All students
 - All clinical staff
 - External researchers

Policy Statement:

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).

Research involving human participants needs to be conducted in a manner which ensures that ethical values and principles are fundamental. The [National Health and Medicine Research Council](#) (NHMRC) require ethical review bodies to be satisfied that the following values are addressed and reflected in the research design: 1) research merit and integrity, 2) justice, 3) beneficence, and 4) respect. Researchers seeking ethical approval and conducting research are required to adhere to the [Values and Principles of Ethical Conduct](#) as stated by the NHMRC.

Ethical clearance for human research is needed to ensure the benefits of the research outweigh the risks of harm to research participants, and to others. Risks include a potential for harm, discomfort or inconvenience. Research will be ethically acceptable only if its potential benefits justify those risks. 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: proposals defined as low risk ethical applications and ethical applications identified as low risk and modifications to research proposals defined as low risk ethical applications. If a low risk application is deemed to have ethical concerns, the application will be reviewed by a full standing HREC meeting. Membership to the Executive Ethics Committee involves:

- The HREC Chair
- One external HREC member
- One Senior Endeavour HREC member

Membership to the Executive Ethics Committee will rotate every six (6) months with the HREC Chair and Senior Endeavour HREC position being standing members to the Committee.

Criteria for projects to be considered by the 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 participants must without exception submit an application for ethical clearance with the HREC. Applications must be completed using the [Human Research Ethics Application \(HREA\)](#) application platform. The completed form and additional documentation must then be submitted via email to the [HREC](#). The HREC Secretariat will review the submission to ensure the correct documentation has been submitted with 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 (7) 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 one (1) of four (4) 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 and negligible 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 HREC secretariat within seven (7) 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 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 HREC Reciprocal Approval Cover Sheet.

Applications for reciprocal ethical clearance will be reviewed by the HREC Chair person. If there are any ethical concerns with the application, the application will be reviewed by, where it has been appointed, the Executive Committee of the HREC. Applicants will receive a response from the HREC Secretariat within seven (7) working days of outcome of their application being decided.

Exemption 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.

Duration of Ethical Clearance

The HREC Secretariat will notify the applicant of ethical approval only when all requested information, clarification or modification have been approved. Notification of ethical approval will be granted in writing to the Chief Investigator of the research proposal. All approved research proposals will be granted ethical clearance for three years. If a longer time frame is required, the Chief Investigator can apply for extended clearance by completing the [HREC Research Project Extension Form](#). The HREC Research Project Extension Form must be submitted to the [HREC Secretariat](#) three (3) months prior to the ethics approval expiration date for the project. Approved research projects can apply for an extension of ethical clearance to the maximum of an additional 12 months. Should an approved research proposal not commence within the three (3) years of ethical clearance, the project will have its ethical clearance revoked and will be required to undergo Full HREC review should the Chief Investigator initiate the project after ethical clearance is revoked.

Rejection of Ethical Clearance

The HREC reserves all rights to reject a research proposal application, should the HREC deem that it does not meet the ethical standards required. The HREC must state clearly the rationale for rejection and provide the researcher with recommendations for amendment. It will be the responsibility of the HREC Secretariat to ensure that all rationale for rejection is directed to the Chief Investigator.

If an application is rejected by the HREC, the researcher may:

- Resubmit the application for full review after the concerns raised by the HREC have been met, and if rejected then
- Request the Research Management Committee review the HREC's decision to reject the application, with a HREC representative present

If the researcher still considers that inadequate consideration has been given to their application after the outcome of any of the above, researchers may make an appeal to the Research Management Committee. If, following the outcome of the review by the Research Management Committee, and the researcher still considers that inadequate consideration has been given, appeal may be made to College Council. If an appeal is made to College Council, after the above process has occurred, the decision made by College Council will be the final arbiter.

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 (1) 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.

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

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.

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

Low risk research – Where the risk, even if unlikely, is more serious than discomfort, the research is not low risk.

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

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

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

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

Supporting Research and Analysis: [Australian Code for the Responsible Conduct of Research 2007](#)

Related Documents: [Academic Governance Framework](#)
[Exemption from Ethics Review Form](#)
[HREC Amendment Application](#)
[HREC Amendment to Approved Proposals](#)
[HREC Complaints Report Form](#)
[HREC Expedited from Ethics Review Application Form](#)
[HREC Low Risk Application Form](#)

[HREC Low Risk Assessment Checklist](#)

[HREC Reciprocal Approval Cover Sheet](#)

[HREC Research Project Annual Report](#)

[HREC Research Project Extension Form](#)

[HREC Research Project Final Report](#)

[Human Research Ethics Application](#)

[National Health and Medicine Research Council \(NHMRC\)](#)

[Research Strategy FY2013 - 2015](#)

[Research Strategy 2014-2016](#)

[Statement on Research Priorities](#)

[Values and Principles of Ethical Conduct](#)

Related Legislation:

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

Guidelines:

[National Statement on Ethical Conduct in Human Research](#)

[Australian Code for the Responsible Conduct of Research
Guidelines approved under Section 95A of the Privacy Act
1988](#)

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

[Human Research Ethics Handbook](#)

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

[National Statement on Ethical Conduct in Human Research](#)

[Office of Research Funding Policy](#)

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

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

[Values and Ethics – Guidelines for Ethical Conduct in Aboriginal
and Torres Strait Islander Health 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