



- All students
- All clinical staff
- External researchers (including external researchers using Endeavour resources)

## Policy Statement:

Human research includes any research conducted with or about people, or their data or tissue. Whilst 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. As such all human research under the auspices of 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 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 (see the footnote on page 1) 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*.

approvalAn 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 HREC composition and functions follow the guidelines outlined in the [\*National Statement\*](#).

## Executive Committee for the HREC

In line with *provision 5.1.20d* of the [National Statement](#), the College may choose to appoint an Executive Committee for the HREC. The Executive Committee streamlines the human research ethics review process and increases the efficiency of the HREC by reducing the volume of matters considered at meetings of the HREC. This allows additional time for discussion of ethical considerations, invitations to and attendance by researchers and continuing professional development. The Executive Committee considers: new proposals defined as involving no greater than a low risk of harm and variations to existing projects where the variations do not introduce new risks or ethical considerations beyond those already reviewed and approved. The Executive Ethics Committee may, in its discretion, refer any proposal to the HREC for review, for example, if a low risk application is deemed to involve more than low risks or to have significant ethical considerations. The membership of the Executive Ethics Committee is:

- The HREC Chair
- One external HREC member
- One internal HREC member

Both the internal and external HREC member of the Executive Ethics Committee will rotate every six months.

## 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
  - Access of students, staff and alumni; or
  - Funding by the College through a Research Grant Program or other allocated funding, as directed by the Office of Research.

## 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 by the Research Management Committee as being of research merit (as defined by the *National Statement*) prior to submission to the HREC.

## Applying for approval ethics approval

Researchers intending to undertake research involving human participants must submit an application for ethics review by approval the HREC. Applications must be completed using the [Human Research Ethics Application](#) (HREA) application platform. For 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. The Research Ethics and Governance Administrator 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 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 of four categories:

1. Accepted without revisions – work on the research project can immediately commence
2. Accepted with minor revisions – revisions should be resubmitted to the Office of Research (or to the Ethics Executive Committee?) to ensure compliance with the HREC's requests/feedback but does not require additional review by the HREC
3. Accepted with major revision requiring additional HREC review – researchers are required to amend their proposed project to accommodate concerns and feedback raised by the 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.

## Exempted Review Process

Research involving children, vulnerable groups, invasive procedures or a sensitive topic must be reviewed by a meeting of the full HREC. Low risk and negligible research may be exempted from ethical review.

Informed by the *National Statement*, the College's policy is that a project must be reviewed by the HREC if it involves:

- A focus on illegal activity or is highly likely to discover illegal activity
- Access to personally identifiable sensitive 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)
- Involves Aboriginal and Torres Strait Islander peoples, groups, communities or issues
- The participation of women who are pregnant, and/or research involving a human fetus
- The participation of 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)
- Most human genomic studies

Applications for expedited review for approval ethics approval will be considered 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 and Governance Administrator within seven working days of a decision being made on their application.

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

## Reciprocal Approval Ethics Approval

Applicants may apply to the College HREC 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 HREC Reciprocal Approval Cover Sheet.

Applications for reciprocal approval ethics approval will be reviewed by the HREC Chairperson. If there are significant 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, including feedback from the Research Ethics and Governance Administrator within seven working days of the decision on their application.

## Exempted ethics approval

Research which involves only existing non-identifiable data and negligible risk is usually eligible for exemption from review. 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 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.

In addition, a review body should retain on file a copy of each research proposal and application for ethical approval, including any information sheets, consent forms or relevant correspondence, in the form in which they were approved. A review body should record decisions about approval, amendment or rejection of proposals in written or electronic form, with reasons for those decisions, linking those reasons to this National Statement

## 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 HRECs **prior** to project commencement. Endeavour's HREC will not grant retrospective approval as it contravenes the requirements of the *National Statement*.

## Duration of Approval ethics approval

The Research Ethics and Governance Administrator 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. If a longer time frame is required, the Chief Investigator can apply for extended approval by completing the HREC Research Project Extension Form. The HREC Research Project Extension Form must be submitted to the [Research Ethics and Governance Administrator](#) three months prior to the ethics approval expiration date for the project. Researchers conducting approved research projects can apply for an extension of approval ethics approval to the maximum of an additional 12 months. Should an approved research proposal not commence within the three years of approval ethics approval, the project will have its approval ethics approval revoked and will be required to undergo Full HREC review should the Chief Investigator initiate the project after approval ethics approval is revoked.

## Rejection of Ethics application

The HREC reserves all rights to reject a research proposal application, should the HREC deem that it does not meet the requirements of the National Statement/College policy. The HREC must state clearly the rationale for rejection and provide the researcher with recommendations for amendment. It will be the responsibility of the Research Ethics and Governance Administrator 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.

## Research ethics implications of student work

Any human research work conducted by a student of the College must be reviewed by the HREC or Executive 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. 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 the person 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/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.

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

Custodian of data:

**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

Australian Catholic University

**Supporting Research and Analysis:**

[Australian Code for the Responsible Conduct of Research 2007](#)

**Related Documents:**

[Academic Governance Framework](#)

[Research Strategy 2013 – 2015](#)

[Research Strategy 2014 – 2016](#)

[Research Strategy 2017 – 2019](#)

[Research Strategy 2020 – 2023](#)

[Statement on Research Priorities](#)

[Exemption from Ethics Review Form](#)

[HREC Amendment Application](#)  
[HREC Amendment to Approved Proposals](#)  
[HREC Complaints Report Form](#)  
[HREC Expedited 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 Final Report](#)

**Related Legislation:**

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

**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 \(2007 updated 2018\)](#)  
[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](#)  
[Ethical conduct in research with Aboriginal and Torres Strait Islander Peoples and communities](#)

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<b>Responsibilities for Implementation:</b>	<ul style="list-style-type: none"> <li>• Associate Director, Research</li> <li>• Research Management Committee</li> </ul>
<b>Key Stakeholders:</b>	<ul style="list-style-type: none"> <li>• Associate Director, Research</li> <li>• All Research Staff</li> <li>• All Academic Staff</li> <li>• External Researchers</li> <li>• Students</li> </ul>